| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2899** | click or scan EU-EC-10009828032 | | 2021-08-30 | Healthcare Professional | EEA | More than 85 Years | Male | Pneumonia (6wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **2900** | click or scan EU-EC-10009828000 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2901** | click or scan EU-EC-10009827999 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2902** | click or scan EU-EC-10009827996 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2903** | click or scan EU-EC-10009827626 | | 2021-08-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**), Suicidal ideation (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2904** | click or scan EU-EC-10009827602 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2905** | click or scan EU-EC-10009827594 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition), Lack of spontaneous speech (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2906** | click or scan EU-EC-10009827580 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Costochondritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2907** | click or scan EU-EC-10009827579 | | 2021-08-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2908** | click or scan EU-EC-10009827182 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2909** | click or scan EU-EC-10009826990 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac tamponade (1d - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [0d - n/a - n/a]) |
| **2910** | click or scan EU-EC-10009826360 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **2911** | click or scan EU-EC-10009826260 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Fluid intake reduced (n/a - Unknown - ), Hypokinesia (n/a - Unknown - ), Mouth breathing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2912** | click or scan EU-EC-10009826256 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Life Threatening), Diarrhoea (n/a - Fatal - **Results in Death**, Life Threatening), Fall (n/a - Fatal - **Results in Death**, Life Threatening), Hypopnoea (n/a - Fatal - **Results in Death**, Life Threatening), Illness (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2913** | click or scan EU-EC-10009826184 | | 2021-08-30 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Anal sex (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - ), Off label use (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **2914** | click or scan EU-EC-10009826148 | | 2021-08-30 | Healthcare Professional | EEA | 18-64 Years | Male | Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **2915** | click or scan EU-EC-10009825948 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cellulitis (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2916** | click or scan EU-EC-10009825784 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2917** | click or scan EU-EC-10009825763 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2918** | click or scan EU-EC-10009825739 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Throat irritation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2919** | click or scan EU-EC-10009825713 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Gastric cancer (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular]) |
| **2920** | click or scan EU-EC-10009825532 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2921** | click or scan EU-EC-10009825529 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Oropharyngeal pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2922** | click or scan EU-EC-10009825524 | | 2021-08-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2923** | click or scan EU-EC-10009825504 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2924** | click or scan EU-EC-10009825499 | | 2021-08-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Upper airway obstruction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2925** | click or scan EU-EC-10009825342 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Somnolence (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2926** | click or scan EU-EC-10009825336 | | 2021-08-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dizziness (n/a - Recovered/Resolved - ), Dysphonia (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2927** | click or scan EU-EC-10009825272 | | 2021-08-30 | Healthcare Professional | Non EEA | Not Specified | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pelvic mass (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2928** | click or scan EU-EC-10009824590 | | 2021-08-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2929** | click or scan EU-EC-10009824496 | | 2021-08-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **2930** | click or scan EU-EC-10009824353 | | 2021-08-29 | Healthcare Professional | EEA | 65-85 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Monoparesis (n/a - Fatal - **Results in Death**), Neck pain (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **2931** | click or scan EU-EC-10009823500 | | 2021-08-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiogenic shock (16h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| **2932** | click or scan EU-EC-10009822600 | | 2021-08-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2933** | click or scan EU-EC-10009822209 | | 2021-08-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 immunisation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Crepitations (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Peripheral coldness (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2934** | click or scan EU-EC-10009822174 | | 2021-08-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiomegaly (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Red man syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - Intramuscular]) |
| **2935** | click or scan EU-EC-10009822065 | | 2021-08-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2936** | click or scan EU-EC-10009821729 | | 2021-08-28 | Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (86d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **2937** | click or scan EU-EC-10009821695 | | 2021-08-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Intestinal infarction (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **2938** | click or scan EU-EC-10009821171 | | 2021-08-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2939** | click or scan EU-EC-10009821169 | | 2021-08-28 | Healthcare Professional | EEA | 18-64 Years | Male | Apraxia (30d - Fatal - **Results in Death**), Coma (30d - Fatal - **Results in Death**), Myocarditis (30d - Fatal - **Results in Death**), Septic shock (30d - Fatal - **Results in Death**), Ventricular dysfunction (30d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **2940** | click or scan EU-EC-10009821145 | | 2021-08-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cholestasis (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Dermatitis exfoliative generalised (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Stevens-Johnson syndrome (n/a - Fatal - **Results in Death**), Subdural haematoma (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **2941** | click or scan EU-EC-10009820194 | | 2021-08-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cough (2d - Fatal - **Results in Death**), Dyspnoea exertional (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| **2942** | click or scan EU-EC-10009819600 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2943** | click or scan EU-EC-10009819491 | | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Male | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **2944** | click or scan EU-EC-10009819433 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2945** | click or scan EU-EC-10009819090 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), Anosmia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2946** | click or scan EU-EC-10009819065 | | 2021-08-27 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **2947** | click or scan EU-EC-10009818889 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2948** | click or scan EU-EC-10009818764 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2949** | click or scan EU-EC-10009818738 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arterial thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Carotid artery thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular insufficiency (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - ), Pupil fixed (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupillary reflex impaired (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vision blurred (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2950** | click or scan EU-EC-10009818476 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2951** | click or scan EU-EC-10009818301 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2952** | click or scan EU-EC-10009818280 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2953** | click or scan EU-EC-10009818039 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2954** | click or scan EU-EC-10009818004 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2955** | click or scan EU-EC-10009817896 | | 2021-08-27 | Non Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2956** | click or scan EU-EC-10009817862 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Acute megakaryocytic leukaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - ), Contusion (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2957** | click or scan EU-EC-10009817708 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2958** | click or scan EU-EC-10009817703 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2959** | click or scan EU-EC-10009817548 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **2960** | click or scan EU-EC-10009817457 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carotid artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2961** | click or scan EU-EC-10009817453 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2962** | click or scan EU-EC-10009817423 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2963** | click or scan EU-EC-10009816935 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Physical deconditioning (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2964** | click or scan<br>EU-EC-10009816815 | | 2021-08-27 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Eczema (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Neoplasm progression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nervous system disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Neurological decompensation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Tumour rupture (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]), KEYTRUDA [PEMBROLIZUMAB] (S - Non-small cell lung cancer - Drug withdrawn - [189d - 200mg - n/a]), PEMETREXED [PEMETREXED, PEMETREXED DISODIUM HEMIPENTAHYDRATE] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]), [CISPLATIN] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]) |
| **2965** | click or scan<br>EU-EC-10009816800 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2966** | click or scan<br>EU-EC-10009816750 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Medication error (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **2967** | click or scan<br>EU-EC-10009815943 | | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (9d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **2968** | click or scan<br>EU-EC-10009815905 | | 2021-08-27 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **2969** | click or scan<br>EU-EC-10009815898 | | 2021-08-27 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **2970** | click or scan<br>EU-EC-10009815893 | | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| **2971** | click or scan<br>EU-EC-10009815889 | | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2972** | click or scan EU-EC-10009815876 | | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2973** | click or scan EU-EC-10009815846 | | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 {DF} - Intramuscular]) |
| **2974** | click or scan EU-EC-10009815712 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Body temperature increased (n/a - Unknown - ), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Cough (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Haemodynamic instability (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2975** | click or scan EU-EC-10009815622 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2976** | click or scan EU-EC-10009815589 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2977** | click or scan EU-EC-10009815451 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Unknown - Life Threatening), Cerebral venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **2978** | click or scan EU-EC-10009815257 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2979** | click or scan EU-EC-10009815253 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2980** | click or scan EU-EC-10009814964 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2981** | click or scan EU-EC-10009814941 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2982** | click or scan EU-EC-10009814791 | | 2021-08-27 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **2983** | click or scan EU-EC-10009814779 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2984** | click or scan EU-EC-10009814698 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown - ), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Eye movement disorder (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Taste disorder (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2985** | click or scan EU-EC-10009814683 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2986** | click or scan EU-EC-10009814682 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intraventricular haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2987** | click or scan EU-EC-10009814680 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Choking (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Regurgitation (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2988** | click or scan EU-EC-10009814678 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Unknown - ), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2989** | click or scan EU-EC-10009814671 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **2990** | click or scan EU-EC-10009814664 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **2991** | click or scan EU-EC-10009814302 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **2992** | click or scan EU-EC-10009813768 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **2993** | click or scan EU-EC-10009812995 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **2994** | click or scan EU-EC-10009812879 | | 2021-08-27 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardiorenal syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **2995** | click or scan EU-EC-10009812399 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2996** | click or scan EU-EC-10009811963 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **2997** | click or scan EU-EC-10009811886 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **2998** | click or scan EU-EC-10009811870 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **2999** | click or scan EU-EC-10009811865 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3000** | click or scan EU-EC-10009811818 | | 2021-08-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3001** | click or scan EU-EC-10009811083 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Ventricular dysfunction (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3002** | click or scan EU-EC-10009810778 | | 2021-08-27 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |



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|---|---|---|---|---|---|---|---|---|---|
| **3003** | click or scan EU-EC-10009810766 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3004** | click or scan EU-EC-10009810736 | | 2021-08-27 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3005** | click or scan EU-EC-10009810600 | | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary arterial stent insertion (n/a - Fatal - **Results in Death**), Percutaneous coronary intervention (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **3006** | click or scan EU-EC-10009809831 | | 2021-08-27 | Non Healthcare Professional | Non EEA | Not Specified | Female | Heart rate increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3007** | click or scan EU-EC-10009809813 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mood altered (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3008** | click or scan EU-EC-10009809667 | | 2021-08-27 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3009** | click or scan EU-EC-10009809633 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Febrile convulsion (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3010** | click or scan EU-EC-10009809608 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3011** | click or scan EU-EC-10009809318 | | 2021-08-27 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death neonatal (n/a - Fatal - **Results in Death**), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**), Premature baby (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **3012** | click or scan EU-EC-10009809308 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3013** | click or scan EU-EC-10009808730 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal distension (n/a - Fatal - **Results in Death**), Abdominal pain upper (n/a - Fatal - **Results in Death**), Anaemia (n/a - Fatal - **Results in Death**), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3014** | click or scan EU-EC-10009808549 | | 2021-08-27 | Non Healthcare Professional | EEA | 65-85 Years | Female | Lumbar vertebral fracture (51d - Fatal - **Results in Death**), Metastases to bone (51d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]) |
| **3015** | click or scan EU-EC-10009807157 | | 2021-08-27 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Clavicle fracture (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Generalised oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3016** | click or scan EU-EC-10009806251 | | 2021-08-27 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3017** | click or scan EU-EC-10009806249 | | 2021-08-27 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (28d - Fatal - **Results in Death**), Cardiac failure (28d - Fatal - **Results in Death**), Headache (28d - Fatal - **Results in Death**), Pneumonia aspiration (28d - Fatal - **Results in Death**), Vertigo (28d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3018** | click or scan EU-EC-10009806094 | | 2021-08-27 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic aneurysm (1d - Fatal - **Results in Death**), Aortic aneurysm rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis (1d - Fatal - **Results in Death**), Asthenia (1d - Fatal - **Results in Death**), Autopsy (1d - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Nausea (1d - Fatal - **Results in Death**), Retroperitoneal haematoma (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (1d - Fatal - **Results in Death**), Vomiting (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3019** | click or scan EU-EC-10009807121 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Immediate post-injection reaction (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3020** | click or scan EU-EC-10009806858 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atypical pneumonia (94d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) |
| **3021** | click or scan EU-EC-10009806745 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell count increased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3022** | click or scan EU-EC-10009806598 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3023** | click or scan EU-EC-10009806354 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3024** | click or scan EU-EC-10009806283 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3025** | click or scan EU-EC-10009805674 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3026** | click or scan EU-EC-10009805401 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**), Cerebrovascular disorder (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Head injury (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Skin laceration (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3027** | click or scan EU-EC-10009804978 | | 2021-08-26 | Non Healthcare Professional | EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cluster headache (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jugular vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Vena cava thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3028** | click or scan EU-EC-10009804810 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3029** | click or scan EU-EC-10009804716 | | 2021-08-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3030** | click or scan EU-EC-10009804592 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Fall (9d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3031** | click or scan EU-EC-10009804534 | | 2021-08-26 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3032** | click or scan EU-EC-10009804510 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (3d - Fatal - **Results in Death**, Other Medically Important Condition), Death (3d - Fatal - **Results in Death**), Fall (3d - Fatal - **Results in Death**, Other Medically Important Condition), Restlessness (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3033** | click or scan EU-EC-10009804333 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**), Physical deconditioning (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **3034** | click or scan EU-EC-10009804332 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3035** | click or scan EU-EC-10009804291 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Cranial nerve disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mitral valve incompetence (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3036** | click or scan EU-EC-10009804101 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | ABEMACICLIB [ABEMACICLIB] (S - Breast cancer metastatic - Unknown - [n/a - n/a - Oral]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3037** | click or scan EU-EC-10009804100 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3038** | click or scan EU-EC-10009804042 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**), Delirium (n/a - Fatal - **Results in Death**), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3039** | click or scan EU-EC-10009804020 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular]) |
| **3040** | click or scan EU-EC-10009803963 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Contusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3041** | click or scan EU-EC-10009803961 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3042** | click or scan EU-EC-10009803874 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - ), Hyperemesis gravidarum (n/a - Unknown - Caused/Prolonged Hospitalisation), Migraine (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3043** | click or scan EU-EC-10009803495 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3044** | click or scan EU-EC-10009803236 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3045** | click or scan EU-EC-10009803152 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3046** | click or scan EU-EC-10009803115 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Recovered/Resolved - ), Decreased appetite (n/a - Recovered/Resolved - ), Sleep disorder (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3047** | click or scan EU-EC-10009802111 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| **3048** | click or scan EU-EC-10009802087 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Male | Pulmonary embolism (25d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - 1{DF} - Intramuscular]) |
| **3049** | click or scan EU-EC-10009802076 | | 2021-08-26 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3050** | click or scan EU-EC-10009802054 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3051** | click or scan EU-EC-10009802051 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3052** | click or scan EU-EC-10009802039 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3053** | click or scan EU-EC-10009802037 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Female | Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation), Body temperature increased (2d - Recovered/Resolved - ), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (2d - Recovered/Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [DROSPIRENONE, ETHINYLESTRADIOL] (S - Contraception - Not applicable - [n/a - n/a - Oral]) |
| **3054** | click or scan EU-EC-10009802027 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Diarrhoea (3d - Recovered/Resolved - ), Pruritus (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3055** | click or scan EU-EC-10009801984 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3056** | click or scan EU-EC-10009801969 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3057** | click or scan EU-EC-10009801946 | | 2021-08-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **3058** | click or scan EU-EC-10009801880 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Blood pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3059** | click or scan EU-EC-10009801855 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3060** | click or scan EU-EC-10009801703 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **3061** | click or scan EU-EC-10009801566 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Fatigue (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3062** | click or scan EU-EC-10009801298 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3063** | click or scan EU-EC-10009801114 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebellar infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle rigidity (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3064** | click or scan EU-EC-10009801097 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3065** | click or scan EU-EC-10009801082 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3066** | click or scan EU-EC-10009800756 | | 2021-08-26 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3067** | click or scan EU-EC-10009800753 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3068** | click or scan EU-EC-10009800748 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3069** | click or scan EU-EC-10009800738 | | 2021-08-26 | Non Healthcare Professional | Non EEA | Not Specified | Male | Gait disturbance (n/a - Unknown - Other Medically Important Condition), Neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3070** | click or scan EU-EC-10009800710 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3071** | click or scan EU-EC-10009799743 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3072** | click or scan EU-EC-10009798983 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anaemia (25d - Fatal - **Results in Death**), Blood urine present (25d - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Renal impairment (25d - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3073** | click or scan EU-EC-10009798961 | | 2021-08-26 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dysphagia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Myasthenia gravis (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3074** | click or scan EU-EC-10009798758 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Mydriasis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **3075** | click or scan EU-EC-10009798622 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3076** | click or scan EU-EC-10009797886 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3077** | click or scan EU-EC-10009797772 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **3078** | click or scan EU-EC-10009797552 | | 2021-08-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3079** | click or scan EU-EC-10009797079 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (8d - Unknown - Caused/Prolonged Hospitalisation), Death (8d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic encephalopathy (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Toxicity to various agents (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Viral infection (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3080** | click or scan EU-EC-10009796894 | | 2021-08-26 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (10d - Fatal - **Results in Death**, Other Medically Important Condition), Chest discomfort (10d - Fatal - **Results in Death**, Other Medically Important Condition), Cough (10d - Fatal - **Results in Death**, Other Medically Important Condition), Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (10d - Fatal - **Results in Death**, Other Medically Important Condition), Hyperhidrosis (10d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (0d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (10d - Fatal - **Results in Death**, Other Medically Important Condition), Rhinorrhoea (10d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **3081** | click or scan EU-EC-10009796700 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3082** | click or scan EU-EC-10009796694 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3083** | click or scan EU-EC-10009796551 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Benign prostatic hyperplasia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bilevel positive airway pressure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothyroidism (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infection (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung infiltration (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3084** | click or scan EU-EC-10009796021 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure decreased (n/a - Unknown - ), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Feeding disorder (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3085** | click or scan EU-EC-10009796018 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3086** | click or scan EU-EC-10009795976 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3087** | click or scan EU-EC-10009795702 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthropod bite (n/a - Unknown - Caused/Prolonged Hospitalisation), Delirium (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Escherichia sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Severe fever with thrombocytopenia syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3088** | click or scan EU-EC-10009795659 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3089** | click or scan EU-EC-10009795255 | | 2021-08-26 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT (Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3090** | click or scan EU-EC-10009795224 | | 2021-08-26 | Non Healthcare Professional | EEA | Not Specified | Male | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3091** | click or scan EU-EC-10009795191 | | 2021-08-26 | Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3092** | click or scan EU-EC-10009795118 | | 2021-08-26 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3093** | click or scan EU-EC-10009795112 | | 2021-08-26 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3094** | click or scan EU-EC-10009794752 | | 2021-08-26 | Healthcare Professional | EEA | 65-85 Years | Male | Terminal state (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **3095** | click or scan EU-EC-10009794486 | | 2021-08-26 | Healthcare Professional | EEA | 18-64 Years | Male | Castleman's disease (89d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3096** | click or scan EU-EC-10009793199 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3097** | click or scan EU-EC-10009793132 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute hepatitis B (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancreatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3098** | click or scan EU-EC-10009791824 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Computerised tomogram abdomen (n/a - Fatal - **Results in Death**), Computerised tomogram abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Gastrointestinal necrosis (n/a - Fatal - **Results in Death**), Intestinal resection (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Surgery (n/a - Fatal - **Results in Death**), Visceral venous thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3099** | click or scan EU-EC-10009791785 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**), Aspiration (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Regurgitation (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3100** | click or scan EU-EC-10009791547 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Splenic artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3101** | click or scan EU-EC-10009791050 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest discomfort (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3102** | click or scan EU-EC-10009790845 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3103** | click or scan EU-EC-10009790710 | | 2021-08-25 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - 1 {DF} - Intramuscular]) |
| **3104** | click or scan EU-EC-10009790631 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **3105** | click or scan EU-EC-10009790617 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Female | Pancytopenia (n/a - Fatal - **Results in Death**), Toxic epidermal necrolysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]), [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (S - Rheumatoid arthritis - n/a - [n/a - 25mg - Subcutaneous]) |
| **3106** | click or scan EU-EC-10009790596 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2 {DF} - Intramuscular]) |
| **3107** | click or scan EU-EC-10009790530 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anxiety (57d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (57d - Fatal - **Results in Death**), Impaired driving ability (57d - Fatal - **Results in Death**), Malaise (57d - Fatal - **Results in Death**), Night sweats (57d - Fatal - **Results in Death**), Pain (57d - Fatal - **Results in Death**), Sarcoma (57d - Fatal - **Results in Death**, Other Medically Important Condition), White blood cell count increased (57d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3108** | click or scan EU-EC-10009790359 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3109** | click or scan EU-EC-10009790215 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (31d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3110** | click or scan EU-EC-10009790123 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Unknown - ), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3111** | click or scan EU-EC-10009789999 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agonal respiration (1d - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (1d - Fatal - **Results in Death**), Coronary artery thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**), Myocardial rupture (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3112** | click or scan EU-EC-10009789930 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3113** | click or scan EU-EC-10009789927 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Hypotension (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3114** | click or scan EU-EC-10009789849 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac tamponade (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3115** | click or scan EU-EC-10009789816 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3116** | click or scan EU-EC-10009789590 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cellulitis (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3117** | click or scan EU-EC-10009789431 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3118** | click or scan EU-EC-10009789136 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (19d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3119** | click or scan EU-EC-10009788937 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2 {DF} - Intramuscular]) |
| **3120** | click or scan EU-EC-10009788927 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3121** | click or scan EU-EC-10009788724 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2[arb'U] - n/a]) |
| **3122** | click or scan EU-EC-10009788694 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3123** | click or scan EU-EC-10009788594 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Oedema (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3124** | click or scan EU-EC-10009788540 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3125** | click or scan EU-EC-10009788469 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3126** | click or scan EU-EC-10009788453 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3127** | click or scan EU-EC-10009788435 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Eating disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3128** | click or scan EU-EC-10009788423 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3129** | click or scan EU-EC-10009788275 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (8d - Fatal - **Results in Death**), Cough (8d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Recovered/Resolved - ), Myalgia (8d - Fatal - **Results in Death**), Pyrexia (8d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3130** | click or scan EU-EC-10009788145 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Hepatic steatosis (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3131** | click or scan EU-EC-10009788104 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autoimmune haemolytic anaemia (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Campylobacter gastroenteritis (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Castleman's disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3132** | click or scan EU-EC-10009787952 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown - More in ICSR]) |
| **3133** | click or scan EU-EC-10009787917 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3134** | click or scan EU-EC-10009787862 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Herpes zoster (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3135** | click or scan EU-EC-10009787788 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Sudden cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3136** | click or scan EU-EC-10009787761 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (1mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (1mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (1mo - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3137** | click or scan EU-EC-10009787712 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - ), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| **3138** | click or scan EU-EC-10009787263 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dementia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Unknown]) |
| **3139** | click or scan EU-EC-10009787246 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Monoplegia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3140** | click or scan EU-EC-10009787186 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Malaise (24d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3141** | click or scan EU-EC-10009787023 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anticoagulant therapy (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal infarct (48d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3142** | click or scan EU-EC-10009786926 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3143** | click or scan EU-EC-10009786743 | | 2021-08-25 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Breast cancer recurrent (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3144** | click or scan EU-EC-10009786728 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3145** | click or scan EU-EC-10009786705 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ), Hypertension (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumoconiosis (17d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3146** | click or scan EU-EC-10009786384 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Female | Malignant hypertension (n/a - Fatal - **Results in Death**), Posterior reversible encephalopathy syndrome (n/a - Fatal - **Results in Death**), Status epilepticus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **3147** | click or scan EU-EC-10009786381 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3148** | click or scan EU-EC-10009786369 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (13d - Fatal - **Results in Death**), Vaccination failure (13d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular]) |
| **3149** | click or scan EU-EC-10009786284 | | 2021-08-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3150** | click or scan EU-EC-10009786152 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Lymphadenopathy (175d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lymphoedema (175d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |



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|---|---|---|---|---|---|---|---|---|---|
| 3151 | click or scan EU-EC-10009786139 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| 3152 | click or scan EU-EC-10009786096 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3153 | click or scan EU-EC-10009786072 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Apallic syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| 3154 | click or scan EU-EC-10009786055 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| 3155 | click or scan EU-EC-10009785933 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3156 | click or scan EU-EC-10009785925 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), OPDIVO [NIVOLUMAB] (S - Oesophageal carcinoma - Unknown - [n/a - n/a - Intravenous (not otherwise specified)]) |
| 3157 | click or scan EU-EC-10009785883 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acidosis (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haematoma (n/a - Recovered/Resolved - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3158 | click or scan EU-EC-10009785790 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3159 | click or scan EU-EC-10009785666 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Angina pectoris (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3160 | click or scan EU-EC-10009785641 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3161** | click or scan EU-EC-10009785640 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pain in extremity (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3162** | click or scan EU-EC-10009785636 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]) |
| **3163** | click or scan EU-EC-10009785629 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3164** | click or scan EU-EC-10009785579 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Sudden cardiac death (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3165** | click or scan EU-EC-10009785427 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3166** | click or scan EU-EC-10009785410 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haematoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Petechiae (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3167** | click or scan EU-EC-10009785373 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3168** | click or scan EU-EC-10009785223 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (17d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3169** | click or scan EU-EC-10009784912 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3170** | click or scan EU-EC-10009784881 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (169d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3171** | click or scan EU-EC-10009784842 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aneurysm (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **3172** | click or scan EU-EC-10009784840 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3173** | click or scan EU-EC-10009784739 | | 2021-08-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Obstructive pancreatitis (10d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3174** | click or scan EU-EC-10009784732 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3175** | click or scan EU-EC-10009784720 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [41d - 2 {DF} - Intramuscular]) |
| **3176** | click or scan EU-EC-10009784710 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bladder catheterisation (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cerebral small vessel ischaemic disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic sinusitis (n/a - Fatal - **Results in Death**), Coma scale (n/a - Fatal - **Results in Death**), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Endotracheal intubation (n/a - Fatal - **Results in Death**), Pulse absent (n/a - Fatal - **Results in Death**), Pulseless electrical activity (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3177** | click or scan EU-EC-10009784677 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [19d - 1 {DF} - Intramuscular]) |
| **3178** | click or scan EU-EC-10009784676 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3179** | click or scan EU-EC-10009784672 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dehydration (n/a - Unknown - ), Face crushing (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3180** | click or scan EU-EC-10009784460 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal discomfort (2d - Fatal - **Results in Death**), Abdominal pain upper (2d - Fatal - **Results in Death**), Back pain (2d - Fatal - **Results in Death**), Myocarditis (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3181** | click or scan EU-EC-10009784162 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (148d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3182** | click or scan EU-EC-10009784026 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3183** | click or scan EU-EC-10009783970 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3184** | click or scan EU-EC-10009783960 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3185** | click or scan EU-EC-10009783817 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3186** | click or scan EU-EC-10009783466 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - ), Back pain (n/a - Not Recovered/Not Resolved - ), Burning sensation (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Gait inability (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Memory impairment (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Thinking abnormal (n/a - Not Recovered/Not Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3187** | click or scan EU-EC-10009783422 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3188** | click or scan EU-EC-10009783401 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Sudden cardiac death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3189** | click or scan EU-EC-10009783373 | | 2021-08-25 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3190** | click or scan EU-EC-10009783298 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (3d - Fatal - **Results in Death**), Death (3d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (3d - Fatal - **Results in Death**), Life support (3d - Fatal - **Results in Death**), Organ donor (3d - Fatal - **Results in Death**), Syncope (3d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3191** | click or scan EU-EC-10009783075 | | 2021-08-25 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3192** | click or scan EU-EC-10009783034 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **3193** | click or scan EU-EC-10009782854 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3194** | click or scan EU-EC-10009782825 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Intestinal haemorrhage (1d - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3195** | click or scan EU-EC-10009782775 | | 2021-08-25 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3196** | click or scan EU-EC-10009782654 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Endotracheal intubation (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Product administered at inappropriate site (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous]) |
| **3197** | click or scan EU-EC-10009782451 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3198** | click or scan EU-EC-10009782302 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event (n/a - Fatal - **Results in Death**), Headache (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Unknown]) |
| **3199** | click or scan EU-EC-10009782236 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Confusional state (1mo - Fatal - **Results in Death**), Cough (1mo - Fatal - **Results in Death**), Dehydration (57d - Fatal - **Results in Death**), Depressed level of consciousness (1mo - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (28d - Fatal - **Results in Death**), Feeling abnormal (1mo - Fatal - **Results in Death**), Feeling hot (1mo - Fatal - **Results in Death**), Insomnia (1mo - Fatal - **Results in Death**), Pyrexia (1mo - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3200** | click or scan EU-EC-10009782199 | | 2021-08-25 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral thrombosis (3070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1309min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (3070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (3070h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3201** | click or scan EU-EC-10009782139 | | 2021-08-25 | Healthcare Professional | Non EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3202** | click or scan EU-EC-10009782080 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3203** | click or scan EU-EC-10009781677 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dermatitis exfoliative generalised (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Psoriasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3204** | click or scan EU-EC-10009781366 | | 2021-08-25 | Healthcare Professional | Non EEA | 18-64 Years | Female | Congestive cardiomyopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3205** | click or scan EU-EC-10009781146 | | 2021-08-25 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Fear (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Insomnia (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3206** | click or scan EU-EC-10009780950 | | 2021-08-25 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3207** | click or scan EU-EC-10009780947 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (6d - Fatal - **Results in Death**), Death (6d - Fatal - **Results in Death**), Oedema peripheral (6d - Fatal - **Results in Death**), Pulmonary embolism (6d - Fatal - **Results in Death**), Respiratory failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3208** | click or scan EU-EC-10009780925 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral ischaemia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombophlebitis superficial (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **3209** | click or scan EU-EC-10009780909 | | 2021-08-25 | Healthcare Professional | EEA | 18-64 Years | Male | Septic shock (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3210** | click or scan EU-EC-10009778476 | | 2021-08-25 | Healthcare Professional | EEA | 65-85 Years | Male | Infection (13d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3211** | click or scan EU-EC-10009780317 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3212** | click or scan EU-EC-10009780218 | | 2021-08-24 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3213** | click or scan EU-EC-10009780133 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3214** | click or scan EU-EC-10009780128 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cor pulmonale (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **3215** | click or scan EU-EC-10009780117 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Gastrointestinal haemorrhage (0d - Fatal - **Results in Death**), Hypotension (0d - Unknown - ), Hypothermia (0d - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3216** | click or scan EU-EC-10009780102 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3217** | click or scan EU-EC-10009780096 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3218** | click or scan EU-EC-10009780084 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (32d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Epistaxis (38d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3219** | click or scan EU-EC-10009780061 | | 2021-08-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (32d - Fatal - **Results in Death**, Life Threatening), Dementia (32d - Fatal - **Results in Death**, Life Threatening), Urinary incontinence (32d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3220** | click or scan EU-EC-10009778826 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3221** | click or scan EU-EC-10009778575 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3222** | click or scan EU-EC-10009778569 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3223** | click or scan EU-EC-10009778017 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a]) |
| **3224** | click or scan EU-EC-10009777955 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3225** | click or scan EU-EC-10009777624 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3226** | click or scan EU-EC-10009777487 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Endocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), VIDAZA [AZACITIDINE] (S - Chronic leukaemia in remission - Not applicable - [9d - n/a - n/a]) |
| **3227** | click or scan EU-EC-10009775660 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3228** | click or scan EU-EC-10009775283 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3229** | click or scan EU-EC-10009775257 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **3230** | click or scan EU-EC-10009775108 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3231** | click or scan<br>EU-EC-10009775094 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| **3232** | click or scan<br>EU-EC-10009775027 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [1d - .3mL - Intramuscular]) |
| **3233** | click or scan<br>EU-EC-10009774995 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **3234** | click or scan<br>EU-EC-10009774982 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Female | Aortic thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3235** | click or scan<br>EU-EC-10009774981 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**), Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3236** | click or scan<br>EU-EC-10009774846 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acidosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ammonia increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Anion gap decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood calcium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood chloride normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatine increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood magnesium increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood potassium normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Carbon dioxide normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Glomerular filtration rate decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemoglobin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell haemoglobin concentration normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell haemoglobin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mean cell volume normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oesophageal variceal ligation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oesophageal varices haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oesophagogastroduodenoscopy abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Packed red blood cell transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet transfusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pupil fixed (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation)... | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3237** | click or scan<br>EU-EC-10009774768 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Antibody test positive (n/a - Unknown - ), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Catatonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immunology test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Sinus disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3238** | click or scan<br>EU-EC-10009774435 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3239** | click or scan EU-EC-10009774366 | | 2021-08-24 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3240** | click or scan EU-EC-10009774321 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3241** | click or scan EU-EC-10009774216 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood creatine phosphokinase increased (n/a - Fatal - **Results in Death**), Bradycardia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Fatal - **Results in Death**), Oliguria (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3242** | click or scan EU-EC-10009774170 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3243** | click or scan EU-EC-10009774122 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3244** | click or scan EU-EC-10009774013 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **3245** | click or scan EU-EC-10009773939 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3246** | click or scan EU-EC-10009773870 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3247** | click or scan EU-EC-10009773810 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Acute abdomen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood lactate dehydrogenase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial necrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sopor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urine output decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]), LEVOFLOXACIN [LEVOFLOXACIN] (S - Dyspnoea - Not applicable - [n/a - 500mg - Oral]) |
| **3248** | click or scan EU-EC-10009773670 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3249** | click or scan EU-EC-10009773649 | | 2021-08-24 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3250** | click or scan EU-EC-10009773280 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Transverse sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3251** | click or scan EU-EC-10009772306 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cyanosis (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Lethargy (n/a - Unknown - ), Peripheral coldness (n/a - Fatal - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3252** | click or scan EU-EC-10009771479 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3253** | click or scan EU-EC-10009771125 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3254** | click or scan EU-EC-10009771120 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3255** | click or scan EU-EC-10009771114 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3256** | click or scan EU-EC-10009771112 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Toothache (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3257** | click or scan EU-EC-10009771110 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myalgia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3258** | click or scan EU-EC-10009771106 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3259** | click or scan EU-EC-10009771105 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3260** | click or scan EU-EC-10009771100 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3261** | click or scan EU-EC-10009771085 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Erythema (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3262** | click or scan EU-EC-10009771023 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3263** | click or scan EU-EC-10009770720 | | 2021-08-24 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Concomitant disease aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemodynamic instability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Livedo reticularis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **3264** | click or scan EU-EC-10009770700 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Fatal - **Results in Death**), Blood pressure immeasurable (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3265** | click or scan EU-EC-10009770629 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3266** | click or scan EU-EC-10009770510 | | 2021-08-24 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arterial occlusive disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hospitalisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Oral candidiasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Peroneal nerve palsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Rales (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3267** | click or scan EU-EC-10009770467 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [28d - .5mL - Intramuscular]) |
| **3268** | click or scan EU-EC-10009769729 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Adrenal insufficiency (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure chronic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Polymyositis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Procalcitonin increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3269** | click or scan EU-EC-10009769724 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (n/a - Fatal - **Results in Death**), Colon gangrene (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Infarction (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal perforation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytosis (n/a - Fatal - **Results in Death**), White blood cell count increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3270** | click or scan EU-EC-10009769708 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3271** | click or scan EU-EC-10009769701 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| **3272** | click or scan EU-EC-10009769554 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [2s - .5mL - Intramuscular]) |
| **3273** | click or scan EU-EC-10009769534 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [84d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3274** | click or scan EU-EC-10009769527 | | 2021-08-24 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3275** | click or scan EU-EC-10009769251 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure chronic (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3276** | click or scan EU-EC-10009768721 | | 2021-08-24 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary congestion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **3277** | click or scan EU-EC-10009768471 | | 2021-08-24 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Gastrointestinal haemorrhage (74d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - ), Tremor (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3278** | click or scan EU-EC-10009768331 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3279** | click or scan EU-EC-10009768281 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3280** | click or scan EU-EC-10009768276 | | 2021-08-24 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Discomfort (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Incontinence (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3281** | click or scan EU-EC-10009768145 | | 2021-08-24 | Healthcare Professional | Non EEA | More than 85 Years | Female | Back pain (n/a - Unknown - ), Cardiac failure (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Mobility decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3282** | click or scan EU-EC-10009767841 | | 2021-08-24 | Healthcare Professional | Non EEA | Not Specified | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - ), Chest pain (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3283** | click or scan EU-EC-10009767522 | | 2021-08-24 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3284** | click or scan EU-EC-10009766547 | | 2021-08-23 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **3285** | click or scan EU-EC-10009765785 | | 2021-08-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3286** | click or scan EU-EC-10009765259 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3287** | click or scan EU-EC-10009765227 | | 2021-08-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (15d - Fatal - **Results in Death**), Drug ineffective (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **3288** | click or scan EU-EC-10009765226 | | 2021-08-23 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **3289** | click or scan EU-EC-10009764904 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3290** | click or scan EU-EC-10009764414 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Demyelination (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3291** | click or scan EU-EC-10009764374 | | 2021-08-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **3292** | click or scan EU-EC-10009764177 | | 2021-08-23 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Diplegia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Paraesthesia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [1d - n/a - Intramuscular]) |
| **3293** | click or scan EU-EC-10009764098 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal function test abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3294** | click or scan EU-EC-10009763655 | | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Headache (n/a - Fatal - **Results in Death**), Hyperthermia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **3295** | click or scan EU-EC-10009763385 | | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Syncope (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3296** | click or scan EU-EC-10009762738 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pancreatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3297** | click or scan EU-EC-10009762734 | | 2021-08-23 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Sinus disorder (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3298** | click or scan EU-EC-10009762469 | | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3299** | click or scan EU-EC-10009762254 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3300** | click or scan EU-EC-10009762198 | | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| **3301** | click or scan EU-EC-10009761377 | | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [85d - 2{DF} - Intramuscular]) |
| **3302** | click or scan EU-EC-10009761334 | | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3303** | click or scan EU-EC-10009761323 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3304** | click or scan EU-EC-10009761309 | | 2021-08-23 | Non Healthcare Professional | EEA | More than 85 Years | Female | Respiratory distress (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| **3305** | click or scan EU-EC-10009761300 | | 2021-08-23 | Non Healthcare Professional | EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular]) |
| **3306** | click or scan EU-EC-10009761246 | | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) |
| **3307** | click or scan EU-EC-10009761245 | | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3308** | click or scan EU-EC-10009761082 | | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3309** | click or scan EU-EC-10009761058 | | 2021-08-23 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| **3310** | click or scan EU-EC-10009761049 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac valve disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3311** | click or scan EU-EC-10009760937 | | 2021-08-23 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Unknown - Other Medically Important Condition), Disorientation (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3312** | click or scan EU-EC-10009760466 | | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Nervous system disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3313** | click or scan EU-EC-10009760425 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Limb discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Off label use (n/a - Unknown - ), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | ZOLEDRONIC ACID [ZOLEDRONIC ACID] (S - Osteoporosis prophylaxis - Not applicable - [n/a - 5mg - Intravenous drip]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3314** | click or scan EU-EC-10009760382 | | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3315** | click or scan EU-EC-10009759722 | | 2021-08-23 | Healthcare Professional | Non EEA | Not Specified | Male | Body temperature decreased (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **3316** | click or scan EU-EC-10009759070 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3317** | click or scan EU-EC-10009758925 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3318** | click or scan EU-EC-10009758584 | | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3319** | click or scan EU-EC-10009758536 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3320** | click or scan EU-EC-10009758530 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3321** | click or scan EU-EC-10009758529 | | 2021-08-23 | Healthcare Professional | Non EEA | 65-85 Years | Female | Autonomic neuropathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3322** | click or scan EU-EC-10009758525 | | 2021-08-23 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3323** | click or scan EU-EC-10009757955 | | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3324** | click or scan EU-EC-10009757741 | | 2021-08-23 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3325** | click or scan EU-EC-10009757735 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Throat irritation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3326** | click or scan EU-EC-10009756733 | | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3327** | click or scan EU-EC-10009756728 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic cardiomyopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3328** | click or scan EU-EC-10009756724 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3329** | click or scan EU-EC-10009756713 | | 2021-08-23 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3330** | click or scan EU-EC-10009756612 | | 2021-08-23 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Arteriosclerosis coronary artery (n/a - Unknown - ), Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Nephrolithiasis (n/a - Unknown - Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pleural effusion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3331** | click or scan EU-EC-10009755271 | | 2021-08-23 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - n/a]) |
| **3332** | click or scan EU-EC-10009754767 | | 2021-08-23 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| **3333** | click or scan EU-EC-10009754766 | | 2021-08-23 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Pyrexia (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| **3334** | click or scan EU-EC-10009753762 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (4d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3335** | click or scan EU-EC-10009753673 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Drug ineffective (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subdural haematoma (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]), LEVETIRACETAM [LEVETIRACETAM] (S - Partial seizures - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]), [HEPARIN, HEPARIN SODIUM] (S - Thrombosis - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]), [IMMUNGLOBULIN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intravenous (not otherwise specified)]) |
| **3336** | click or scan EU-EC-10009753574 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (14d - Fatal - **Results in Death**), Headache (n/a - Unknown - **Results in Death**), Intracranial pressure increased (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3337** | click or scan EU-EC-10009753556 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Coronary artery dissection (7d - Fatal - **Results in Death**), Fatigue (n/a - Unknown - **Results in Death**), Joint swelling (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3338** | click or scan EU-EC-10009753537 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3339** | click or scan EU-EC-10009753533 | | 2021-08-21 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anti-neutrophil cytoplasmic antibody positive vasculitis (53d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary vasculitis (53d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal vasculitis (53d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (53d - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3340** | click or scan EU-EC-10009753524 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (1d - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - n/a]) |
| **3341** | click or scan EU-EC-10009753404 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3342** | click or scan EU-EC-10009753258 | | 2021-08-21 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3343** | click or scan EU-EC-10009753072 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cardiac death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Chronic obstructive pulmonary disease (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Heart rate increased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hypertension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Pulmonary oedema (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **3344** | click or scan EU-EC-10009753069 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3345** | click or scan EU-EC-10009753068 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **3346** | click or scan EU-EC-10009753067 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Basilar artery thrombosis (6d - Fatal - **Results in Death**), Brain stem stroke (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Nausea (n/a - Not Recovered/Not Resolved - **Results in Death**), Visual impairment (n/a - Not Recovered/Not Resolved - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3347** | click or scan EU-EC-10009753066 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Pancreatic cyst (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **3348** | click or scan EU-EC-10009753065 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute coronary syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3349** | click or scan EU-EC-10009753056 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cardiac disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Cerebral disorder (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Groin pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3350** | click or scan EU-EC-10009753053 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Ear infection (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Neck pain (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3351** | click or scan EU-EC-10009753048 | | 2021-08-21 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anisocytosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disseminated intravascular coagulation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Polychromasia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3352** | click or scan EU-EC-10009753045 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Body temperature decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (23d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersomnia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3353** | click or scan EU-EC-10009751586 | | 2021-08-21 | Healthcare Professional | EEA | 65-85 Years | Female | Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Musculoskeletal pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3354** | click or scan EU-EC-10009751330 | | 2021-08-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Blood albumin decreased (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3355** | click or scan EU-EC-10009751290 | | 2021-08-21 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (25d - Fatal - **Results in Death**), Chest pain (25d - Fatal - **Results in Death**), Cough (25d - Fatal - **Results in Death**), Diarrhoea (25d - Fatal - **Results in Death**), Dyspnoea (25d - Fatal - **Results in Death**), Extrasystoles (25d - Fatal - **Results in Death**), Hyperhidrosis (25d - Fatal - **Results in Death**), Oxygen saturation decreased (25d - Fatal - **Results in Death**), Rales (25d - Fatal - **Results in Death**), Weight decreased (25d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **3356** | click or scan EU-EC-10009750890 | | 2021-08-21 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3357** | click or scan EU-EC-10009750320 | | 2021-08-20 | Healthcare Professional | Non EEA | Not Specified | Female | Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3358** | click or scan EU-EC-10009750319 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Female | Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3359** | click or scan EU-EC-10009750078 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 pneumonia (3d - Fatal - **Results in Death**, Life Threatening), Intestinal ischaemia (3d - Fatal - **Results in Death**, Life Threatening), Vaccination failure (3d - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3360** | click or scan EU-EC-10009749750 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**), Dementia Alzheimer's type (n/a - Fatal - **Results in Death**), Depression (n/a - Not Recovered/Not Resolved - ), Haemorrhage intracranial (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Incomplete course of vaccination (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Not applicable - [n/a - n/a - Intramuscular]) |
| **3361** | click or scan EU-EC-10009749639 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3362** | click or scan EU-EC-10009749464 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral mass effect (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3363** | click or scan EU-EC-10009749428 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3364** | click or scan EU-EC-10009749285 | | 2021-08-20 | Healthcare Professional | EEA | More than 85 Years | Male | Coronary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3365** | click or scan EU-EC-10009749190 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dysphonia (2d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**), Oropharyngeal pain (2d - Fatal - **Results in Death**), Pollakiuria (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3366** | click or scan EU-EC-10009748962 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaemia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Hyporesponsive to stimuli (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3367** | click or scan EU-EC-10009748956 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3368** | click or scan EU-EC-10009748810 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3369** | click or scan EU-EC-10009748664 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3370** | click or scan EU-EC-10009748655 | | 2021-08-20 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (18d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3371** | click or scan EU-EC-10009748643 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3372** | click or scan EU-EC-10009748629 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cranial nerve disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3373** | click or scan EU-EC-10009748561 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3374** | click or scan EU-EC-10009748558 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3375** | click or scan EU-EC-10009748544 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3376** | click or scan EU-EC-10009748543 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain upper (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3377** | click or scan EU-EC-10009748256 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3378** | click or scan EU-EC-10009748182 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - ), Blood pressure fluctuation (n/a - Unknown - ), Chills (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**), Tremor (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3379** | click or scan EU-EC-10009748096 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **3380** | click or scan EU-EC-10009748041 | | 2021-08-20 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Diarrhoea (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (15d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3381** | click or scan EU-EC-10009748040 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (18d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3382** | click or scan EU-EC-10009748039 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3383** | click or scan EU-EC-10009748021 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Female | Pancreatic carcinoma (77d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3384** | click or scan EU-EC-10009748004 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **3385** | click or scan EU-EC-10009747981 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Vaccination site erythema (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3386** | click or scan EU-EC-10009747959 | | 2021-08-20 | Non Healthcare Professional | EEA | 18-64 Years | Male | Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3387** | click or scan EU-EC-10009747951 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aphthous ulcer (3d - Fatal - **Results in Death**), Pain in extremity (3d - Fatal - **Results in Death**), Rash (3d - Fatal - **Results in Death**), Tongue oedema (3d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - .5mL - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INDAPAMIDE, PERINDOPRIL ARGININE, PERINDOPRIL TERT-BUTYLAMINE, INDAPAMIDE] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [NEBIVOLOL] (S - Product used for unknown indication - n/a - [n/a - n/a - n/a]) |
| **3388** | click or scan EU-EC-10009747921 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3389** | click or scan EU-EC-10009747918 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Irritability (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3390** | click or scan EU-EC-10009747801 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3391** | click or scan EU-EC-10009747699 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Drooling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gaze palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3392** | click or scan EU-EC-10009747688 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3393** | click or scan EU-EC-10009747326 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic shock (5h - Fatal - **Results in Death**), Cardiac failure acute (5h - Fatal - **Results in Death**), Pancytopenia (5h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1[arb'U] - n/a]) |
| **3394** | click or scan EU-EC-10009747228 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3395** | click or scan EU-EC-10009746965 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary artery occlusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3396** | click or scan EU-EC-10009746928 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abscess (n/a - Unknown - ), Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Unknown - Other Medically Important Condition), Febrile convulsion (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Toxic shock syndrome (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3397** | click or scan EU-EC-10009746683 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3398** | click or scan EU-EC-10009746659 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Heat illness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3399** | click or scan EU-EC-10009746385 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3400** | click or scan EU-EC-10009746282 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Unknown - Other Medically Important Condition), Delirium (n/a - Unknown - Other Medically Important Condition), Hallucination (n/a - Unknown - Other Medically Important Condition), Hypercapnia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Pneumonia staphylococcal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3401** | click or scan EU-EC-10009746205 | | 2021-08-20 | Non Healthcare Professional | Non EEA | Not Specified | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - n/a]) |
| **3402** | click or scan EU-EC-10009745976 | | 2021-08-20 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3403** | click or scan EU-EC-10009745913 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3404** | click or scan EU-EC-10009745912 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pain (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3405** | click or scan EU-EC-10009745030 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Female | Condition aggravated (34d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Rash (34d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [5s - 1 {DF} - Intramuscular]) |
| **3406** | click or scan EU-EC-10009744951 | | 2021-08-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemoptysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3407** | click or scan EU-EC-10009744624 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3408** | click or scan EU-EC-10009744611 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3409** | click or scan EU-EC-10009744425 | | 2021-08-20 | Healthcare Professional | EEA | 65-85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **3410** | click or scan EU-EC-10009744113 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Blindness (n/a - Unknown - Disabling, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3411** | click or scan EU-EC-10009744064 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **3412** | click or scan EU-EC-10009743750 | | 2021-08-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Endocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3413** | click or scan EU-EC-10009743414 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Heart rate increased (n/a - Unknown - ), Local reaction (n/a - Unknown - ), Toxic shock syndrome (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3414** | click or scan EU-EC-10009743392 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Not Recovered/Not Resolved - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3415** | click or scan EU-EC-10009743388 | | 2021-08-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Internal haemorrhage (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3416** | click or scan EU-EC-10009743385 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3417** | click or scan EU-EC-10009743128 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Epilepsy (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [CARBAMAZEPINE] (S - Epilepsy - Dose reduced - [n/a - n/a - n/a]) |
| **3418** | click or scan EU-EC-10009743060 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - ), Cardiogenic shock (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Hypersomnia (n/a - Unknown - ), Illness (n/a - Unknown - ), Incoherent (n/a - Unknown - ), Malaise (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3419** | click or scan EU-EC-10009742891 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bone pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Surgery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **3420** | click or scan EU-EC-10009742890 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3421** | click or scan EU-EC-10009742844 | | 2021-08-20 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Oropharyngeal pain (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3422** | click or scan EU-EC-10009742744 | | 2021-08-20 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3423** | click or scan EU-EC-10009742477 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure increased (0d - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Injection site pain (2d - Recovered/Resolved - ), Syncope (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3424** | click or scan EU-EC-10009742330 | | 2021-08-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (1d - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coordination abnormal (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dysarthria (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - ), Paralysis (n/a - Unknown - ), Speech disorder (n/a - Unknown - ), Thrombosis (1d - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3425** | click or scan EU-EC-10009742284 | | 2021-08-20 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3426** | click or scan EU-EC-10009742281 | | 2021-08-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3427** | click or scan EU-EC-10009742278 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3428** | click or scan EU-EC-10009742067 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3429** | click or scan EU-EC-10009741976 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3430** | click or scan EU-EC-10009741302 | | 2021-08-20 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Transient ischaemic attack (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3431** | click or scan EU-EC-10009740956 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Enterocolitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal perforation (n/a - Fatal - **Results in Death**), Peritonitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vasculitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3432** | click or scan EU-EC-10009740948 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3433** | click or scan EU-EC-10009740944 | | 2021-08-20 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - ), Embolic cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3434** | click or scan EU-EC-10009740936 | | 2021-08-20 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Fatal - **Results in Death**), Ileus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3435** | click or scan EU-EC-10009740912 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Confusional state (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **3436** | click or scan EU-EC-10009740770 | | 2021-08-20 | Non Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3437** | click or scan EU-EC-10009739831 | | 2021-08-20 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Language disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **3438** | click or scan EU-EC-10009739791 | | 2021-08-20 | Healthcare Professional | EEA | 18-64 Years | Male | Anaemia (14d - Fatal - **Results in Death**), Epistaxis (14d - Fatal - **Results in Death**), Thrombocytopenia (14d - Fatal - **Results in Death**), Thrombotic thrombocytopenic purpura (14d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **3439** | click or scan EU-EC-10009739337 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3440** | click or scan EU-EC-10009739328 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (9d - Fatal - **Results in Death**), Cough (9d - Unknown - ), Pyrexia (9d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3441** | click or scan EU-EC-10009739319 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (34d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3442** | click or scan EU-EC-10009739316 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Circulatory collapse (10d - Fatal - **Results in Death**), Cough (10d - Unknown - ), Dyspnoea (10d - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3443** | click or scan EU-EC-10009739313 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3444** | click or scan EU-EC-10009739115 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arterial thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visceral venous thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [n/a - n/a - Intramuscular]) |
| **3445** | click or scan EU-EC-10009739013 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure abnormal (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Body temperature increased (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypothermia (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Irritability (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lethargy (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral coldness (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal injury (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary retention (75d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3446** | click or scan EU-EC-10009739007 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Leukopenia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3447** | click or scan EU-EC-10009738765 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3448** | click or scan EU-EC-10009738583 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **3449** | click or scan EU-EC-10009738273 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3450** | click or scan EU-EC-10009738272 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Diarrhoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Tachypnoea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3451** | click or scan EU-EC-10009738262 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3452** | click or scan EU-EC-10009738214 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Back pain (n/a - Not Recovered/Not Resolved - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neck pain (n/a - Not Recovered/Not Resolved - ), Pulmonary thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3453** | click or scan EU-EC-10009738204 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pericardial haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3454** | click or scan EU-EC-10009738194 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypopnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3455** | click or scan EU-EC-10009738192 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3456** | click or scan EU-EC-10009737693 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3457** | click or scan EU-EC-10009737621 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Septic shock (5d - Fatal - **Results in Death**), Thrombocytopenia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3458** | click or scan EU-EC-10009737613 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (19d - Fatal - **Results in Death**), Pneumonia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3459** | click or scan EU-EC-10009737388 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3460** | click or scan EU-EC-10009736640 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination complication (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3461** | click or scan EU-EC-10009736638 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Computerised tomogram (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3462** | click or scan EU-EC-10009735183 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Not Specified | Sudden cardiac death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3463** | click or scan EU-EC-10009734866 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [36d - 1 {DF} - Intramuscular]) |
| **3464** | click or scan EU-EC-10009734848 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1 {DF} - Intramuscular]) |
| **3465** | click or scan EU-EC-10009734847 | | 2021-08-19 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Confusional state (6d - Fatal - **Results in Death**), Interstitial lung disease (6d - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [37d - 1 {DF} - Intramuscular]) |
| **3466** | click or scan EU-EC-10009734793 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3467** | click or scan EU-EC-10009734769 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]), RITUXIMAB [RITUXIMAB] (S - Muscular weakness - Dose not changed - [n/a - 1 {DF} - Intravenous (not otherwise specified)]) |
| **3468** | click or scan EU-EC-10009734643 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3469** | click or scan EU-EC-10009734505 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3470** | click or scan EU-EC-10009734500 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Male | Atrial fibrillation (3d - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Metabolic acidosis (3d - Fatal - **Results in Death**), Shock (3d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3471** | click or scan EU-EC-10009734494 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary fibrosis (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3472** | click or scan EU-EC-10009734492 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3473** | click or scan EU-EC-10009734355 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Bronchospasm (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic lesion (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pulmonary mass (n/a - Unknown - Other Medically Important Condition), Renal function test abnormal (n/a - Unknown - ), Wheezing (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3474** | click or scan EU-EC-10009734322 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (n/a - Unknown - ), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Blood alkaline phosphatase decreased (n/a - Unknown - ), Blood creatinine decreased (n/a - Unknown - ), Blood thyroid stimulating hormone decreased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Cardiothoracic ratio increased (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - ), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematocrit decreased (n/a - Unknown - ), Haemoglobin decreased (n/a - Unknown - ), Lymphocyte count decreased (n/a - Unknown - ), Malaise (n/a - Unknown - ), Mean cell haemoglobin concentration decreased (n/a - Unknown - ), Mean cell volume decreased (n/a - Unknown - ), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Orthopnoea (n/a - Unknown - ), Pallor (n/a - Unknown - ), Red blood cell count decreased (n/a - Unknown - ), Reticulocyte count decreased (n/a - Unknown - ), Ventricular failure (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3475** | click or scan EU-EC-10009734290 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dependence on respirator (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3476** | click or scan<br>EU-EC-10009734258 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Unknown - Caused/Prolonged Hospitalisation), Glycosylated haemoglobin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sputum purulent (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3477** | click or scan<br>EU-EC-10009734253 | | 2021-08-19 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3478** | click or scan<br>EU-EC-10009733462 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral infarction (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eczema (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malignant neoplasm progression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nervous system disorder (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological decompensation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), KEYTRUDA [PEMBROLIZUMAB] (S - Non-small cell lung cancer - Drug withdrawn - [n/a - 200mg - n/a]), KEYTRUDA [PEMBROLIZUMAB] (S - n/a - Drug withdrawn - [166d - 200mg - n/a]), PEMETREXED [PEMETREXED, PEMETREXED DISODIUM HEMIPENTAHYDRATE] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]), [CISPLATIN] (S - Non-small cell lung cancer - Drug withdrawn - [45d - n/a - n/a]) |
| **3479** | click or scan<br>EU-EC-10009733313 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3480** | click or scan<br>EU-EC-10009733307 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3481** | click or scan<br>EU-EC-10009733294 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3482** | click or scan<br>EU-EC-10009733292 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3483** | click or scan EU-EC-10009733281 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3484** | click or scan EU-EC-10009732735 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3485** | click or scan EU-EC-10009732159 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - ), Respiratory failure (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3486** | click or scan EU-EC-10009731417 | | 2021-08-19 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Haemorrhage (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3487** | click or scan EU-EC-10009730786 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abortion missed (n/a - Fatal - **Results in Death**, Congenital Anomaly) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3488** | click or scan EU-EC-10009730781 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Large intestine perforation (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3489** | click or scan EU-EC-10009730630 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3490** | click or scan EU-EC-10009730511 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Blood glucose increased (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3491** | click or scan EU-EC-10009730130 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (1d - Fatal - **Results in Death**), Stomatitis (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3492** | click or scan EU-EC-10009730013 | | 2021-08-19 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Brain death (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral thrombosis (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Endocarditis (n/a - Fatal - **Results in Death**), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Fatal - **Results in Death**), Hypoxia (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Mutism (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Pupils unequal (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3493** | click or scan EU-EC-10009729913 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (1d - Fatal - **Results in Death**), Carditis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Inflammation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3494** | click or scan EU-EC-10009729332 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (31d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3495** | click or scan EU-EC-10009729253 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3496** | click or scan EU-EC-10009728904 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis coronary artery (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cerebral arteriosclerosis (n/a - Unknown - Other Medically Important Condition), Emphysema (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Pneumothorax (n/a - Fatal - **Results in Death**), Traumatic haemothorax (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3497** | click or scan EU-EC-10009728791 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Coronary artery thrombosis (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Tuberculosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **3498** | click or scan EU-EC-10009728763 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3499** | click or scan EU-EC-10009728661 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3500** | click or scan EU-EC-10009728625 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Leukaemia (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Walking aid user (42d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3501** | click or scan EU-EC-10009728565 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aphasia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain injury (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic stroke (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immediate post-injection reaction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3502** | click or scan EU-EC-10009728420 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Rib fracture (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3503** | click or scan EU-EC-10009728175 | | 2021-08-19 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myelitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3504** | click or scan EU-EC-10009728123 | | 2021-08-19 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **3505** | click or scan EU-EC-10009727998 | | 2021-08-19 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3506** | click or scan EU-EC-10009727523 | | 2021-08-19 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute hepatic failure (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Haemophagocytic lymphohistiocytosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperferritinaemia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia legionella (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3507** | click or scan EU-EC-10009727488 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Male | Hyperpyrexia (10d - Fatal - **Results in Death**), Respiratory failure (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3508** | click or scan EU-EC-10009727473 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Infection (n/a - Fatal - **Results in Death**), Respiratory fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Subcutaneous]) |
| **3509** | click or scan EU-EC-10009727433 | | 2021-08-19 | Healthcare Professional | EEA | More than 85 Years | Female | Peripheral ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3510** | click or scan EU-EC-10009727383 | | 2021-08-19 | Healthcare Professional | EEA | Not Specified | Male | Thrombocytopenia (7d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3511** | click or scan EU-EC-10009727378 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **3512** | click or scan EU-EC-10009727372 | | 2021-08-19 | Healthcare Professional | EEA | 18-64 Years | Female | Haemorrhagic pneumonia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3513** | click or scan EU-EC-10009727362 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (10d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3514** | click or scan EU-EC-10009727358 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3515** | click or scan EU-EC-10009727355 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3516** | click or scan EU-EC-10009727351 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac disorder (95d - Fatal - **Results in Death**), Pulmonary embolism (95d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **3517** | click or scan EU-EC-10009727348 | | 2021-08-19 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Hypertensive crisis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3518** | click or scan EU-EC-10009727344 | | 2021-08-19 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3519** | click or scan EU-EC-10009727316 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Female | Myalgia (2d - Fatal - **Results in Death**), Myocardial infarction (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3520** | click or scan EU-EC-10009727312 | | 2021-08-19 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3521** | click or scan EU-EC-10009727125 | | 2021-08-19 | Non Healthcare Professional | EEA | More than 85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3522** | click or scan EU-EC-10009726819 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardioversion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Resuscitation (n/a - Fatal - **Results in Death**), Snoring (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3523** | click or scan EU-EC-10009726294 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (6d - Fatal - **Results in Death**, Other Medically Important Condition), Coma (6d - Fatal - **Results in Death**, Other Medically Important Condition), Death (6d - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (6d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3524** | click or scan EU-EC-10009726045 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **3525** | click or scan EU-EC-10009726015 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3526** | click or scan EU-EC-10009725843 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Male | Meningoradiculitis (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3527** | click or scan EU-EC-10009725547 | | 2021-08-18 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3528** | click or scan EU-EC-10009725489 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Muscular weakness (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3529** | click or scan EU-EC-10009724979 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Unknown - ), Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac death (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Constipation (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lack of spontaneous speech (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Mouth haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Rash (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**), Sneezing (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3530** | click or scan EU-EC-10009724964 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal distension (n/a - Recovering/Resolving - ), Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Choking (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mouth breathing (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Recovering/Resolving - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - ), Respiratory disorder (n/a - Recovering/Resolving - ), Vomiting (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3531** | click or scan EU-EC-10009724832 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3532** | click or scan EU-EC-10009724563 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - ), Coordination abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dysarthria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Encephalitis viral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Epilepsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Meningoencephalitis viral (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), White blood cell count increased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3533** | click or scan EU-EC-10009724559 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Choking (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Reduced facial expression (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination complication (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3534** | click or scan EU-EC-10009724411 | | 2021-08-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3535** | click or scan EU-EC-10009724099 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3536** | click or scan EU-EC-10009723880 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3537** | click or scan EU-EC-10009723876 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Plasmodium vivax infection (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3538** | click or scan EU-EC-10009723846 | | 2021-08-18 | Healthcare Professional | EEA | Not Specified | Female | Arteriosclerosis (n/a - Fatal - **Results in Death**), Hypercholesterolaemia (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **3539** | click or scan EU-EC-10009723812 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aneurysm ruptured (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3540** | click or scan EU-EC-10009723644 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (68d - Fatal - **Results in Death**, Other Medically Important Condition), Hepatic encephalopathy (68d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3541** | click or scan EU-EC-10009723405 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3542** | click or scan EU-EC-10009723324 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Autopsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epstein-Barr virus infection (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Histology (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vasculitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3543** | click or scan EU-EC-10009723293 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic valve stenosis (7d - Fatal - **Results in Death**), Cardiac failure (7d - Fatal - **Results in Death**, Other Medically Important Condition), Emphysema (7d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3544** | click or scan EU-EC-10009723279 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3545** | click or scan EU-EC-10009723275 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3546** | click or scan EU-EC-10009723162 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 1 {DF} - Intramuscular]) |
| **3547** | click or scan EU-EC-10009723158 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (6d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [60d - 1 {DF} - Intramuscular]) |
| **3548** | click or scan EU-EC-10009723106 | | 2021-08-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **3549** | click or scan EU-EC-10009722967 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [71d - 1 {DF} - Intramuscular]) |
| **3550** | click or scan EU-EC-10009722544 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Reaction to excipient (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3551** | click or scan EU-EC-10009722280 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3552** | click or scan EU-EC-10009721232 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3553** | click or scan EU-EC-10009721192 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (2d - Fatal - **Results in Death**, Other Medically Important Condition), Delirium (2d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (2d - Fatal - **Results in Death**), Panic attack (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3554** | click or scan EU-EC-10009721130 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3555** | click or scan EU-EC-10009720952 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3556** | click or scan EU-EC-10009720841 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (27d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3557** | click or scan EU-EC-10009720596 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3558** | click or scan EU-EC-10009720593 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3559** | click or scan EU-EC-10009720583 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3560** | click or scan EU-EC-10009720578 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3561** | click or scan EU-EC-10009720567 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3562** | click or scan EU-EC-10009720256 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3563** | click or scan EU-EC-10009720229 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3564** | click or scan EU-EC-10009720226 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Angioedema (1d - Recovered/Resolved - Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Hypersensitivity (1d - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3565** | click or scan EU-EC-10009720165 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac output decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypophagia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3566** | click or scan EU-EC-10009719961 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3567** | click or scan EU-EC-10009719651 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Pulse abnormal (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3568** | click or scan EU-EC-10009719588 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Stupor (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3569** | click or scan EU-EC-10009719549 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3570** | click or scan EU-EC-10009719116 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3571** | click or scan EU-EC-10009718778 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Ischaemic cardiomyopathy (n/a - Fatal - **Results in Death**), Urosepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a]) |
| **3572** | click or scan EU-EC-10009718757 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Systemic inflammatory response syndrome (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3573** | click or scan EU-EC-10009718705 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3574** | click or scan EU-EC-10009718563 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3575** | click or scan EU-EC-10009718186 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Influenza like illness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3576** | click or scan EU-EC-10009718048 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - ), Mental status changes (1d - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (1d - Unknown - Caused/Prolonged Hospitalisation), Surgery (12d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3577** | click or scan EU-EC-10009717833 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypopnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Osteomyelitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3578** | click or scan EU-EC-10009717800 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3579** | click or scan EU-EC-10009717788 | | 2021-08-18 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3580** | click or scan EU-EC-10009717656 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cholecystitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Liver disorder (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tachycardia (0d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3581** | click or scan EU-EC-10009717647 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - Life Threatening), Hypertension (n/a - Fatal - **Results in Death**, Life Threatening), Maternal exposure during pregnancy (n/a - Unknown - Life Threatening), Nausea (n/a - Unknown - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3582** | click or scan EU-EC-10009717633 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mobility decreased (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3583** | click or scan EU-EC-10009717604 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Choking (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Unknown - ), Speech disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3584** | click or scan EU-EC-10009717514 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Embolic stroke (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Hospitalisation (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3585** | click or scan EU-EC-10009717480 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3586** | click or scan EU-EC-10009716959 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Discomfort (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3587** | click or scan EU-EC-10009716898 | | 2021-08-18 | Non Healthcare Professional | EEA | 18-64 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (2d - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (2d - Fatal - **Results in Death**), Disseminated intravascular coagulation (2d - Fatal - **Results in Death**), Platelet count decreased (2d - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - Subcutaneous]) |
| **3588** | click or scan EU-EC-10009716897 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **3589** | click or scan EU-EC-10009716896 | | 2021-08-18 | Healthcare Professional | EEA | Not Specified | Not Specified | Death neonatal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transplacental]) |
| **3590** | click or scan EU-EC-10009716850 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3591** | click or scan EU-EC-10009716810 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3592** | click or scan EU-EC-10009716770 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3593** | click or scan EU-EC-10009716615 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3594** | click or scan EU-EC-10009716572 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (3d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3595** | click or scan EU-EC-10009716474 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3596** | click or scan EU-EC-10009716117 | | 2021-08-18 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Arthralgia (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Erythema (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Hiatus hernia (n/a - Unknown - ), Illness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Other Medically Important Condition), Vaccination complication (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3597** | click or scan EU-EC-10009716052 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3598** | click or scan EU-EC-10009715734 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Male | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Cardiomegaly (n/a - Fatal - **Results in Death**), Myocardial fibrosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3599** | click or scan EU-EC-10009715731 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Groin pain (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3600** | click or scan EU-EC-10009715631 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Female | Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3601** | click or scan EU-EC-10009715624 | | 2021-08-18 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3602** | click or scan EU-EC-10009715619 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3603** | click or scan EU-EC-10009715618 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Male | Illness (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3604** | click or scan EU-EC-10009715612 | | 2021-08-18 | Healthcare Professional | Non EEA | More than 85 Years | Female | Fall (n/a - Fatal - **Results in Death**), Lower respiratory tract infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3605** | click or scan EU-EC-10009715424 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Blood pressure increased (n/a - Unknown - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Ischaemia (n/a - Unknown - ), Lung disorder (n/a - Unknown - ), Renal disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3606** | click or scan EU-EC-10009715421 | | 2021-08-18 | Non Healthcare Professional | Non EEA | Not Specified | Female | Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3607** | click or scan EU-EC-10009715042 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3608** | click or scan EU-EC-10009714961 | | 2021-08-18 | Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (18d - Fatal - **Results in Death**), Nausea (18d - Fatal - **Results in Death**), Pyrexia (18d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **3609** | click or scan EU-EC-10009714711 | | 2021-08-18 | Healthcare Professional | EEA | 18-64 Years | Male | Hyperpyrexia (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **3610** | click or scan EU-EC-10009714430 | | 2021-08-18 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (10d - Fatal - **Results in Death**), Diarrhoea (10d - Fatal - **Results in Death**), Dyspnoea (10d - Fatal - **Results in Death**), Fatigue (10d - Fatal - **Results in Death**), Lung opacity (10d - Fatal - **Results in Death**), Nausea (10d - Fatal - **Results in Death**), Pain (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3611** | click or scan EU-EC-10009713051 | | 2021-08-18 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - ), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Joint stiffness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3612** | click or scan EU-EC-10009714260 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3613** | click or scan EU-EC-10009713988 | | 2021-08-17 | Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3614** | click or scan EU-EC-10009713543 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure congestive (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3615** | click or scan EU-EC-10009713161 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Acute hepatic failure (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Neurological decompensation (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (23d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3616** | click or scan EU-EC-10009712759 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3617** | click or scan EU-EC-10009712593 | | 2021-08-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3618** | click or scan EU-EC-10009712345 | | 2021-08-17 | Healthcare Professional | EEA | 18-64 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriovenous fistula maturation failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Fatal - **Results in Death**), Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Factor V Leiden mutation (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - **Results in Death**), Hyperlipidaemia (n/a - Fatal - **Results in Death**), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Muscular weakness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Noninfective encephalitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary artery thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory depression (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic vein thrombosis (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination complication (n/a - Fatal - **Results in Death**), Vision blurred (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Visual impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3619** | click or scan EU-EC-10009712240 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - ), Syncope (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3620** | click or scan EU-EC-10009712179 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (n/a - Unknown - ), Arthralgia (n/a - Unknown - ), Delirium (n/a - Unknown - ), Ecchymosis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - Life Threatening), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Sputum retention (n/a - Unknown - Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **3621** | click or scan EU-EC-10009712108 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3622** | click or scan EU-EC-10009712005 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Incorrect route of product administration (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Platelet count decreased (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - 1{DF} - Intravenous (not otherwise specified)]) |
| **3623** | click or scan EU-EC-10009711938 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anal incontinence (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (1d - Fatal - **Results in Death**), Pupillary reflex impaired (0d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Respiratory arrest (0d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular - More in ICSR]) |
| **3624** | click or scan EU-EC-10009711563 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Dehydration (n/a - Fatal - **Results in Death**), Enterocolitis (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3625** | click or scan EU-EC-10009711303 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3626** | click or scan EU-EC-10009711211 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (11d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (10d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3627** | click or scan EU-EC-10009711180 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain death (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage intracranial (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Motor dysfunction (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Organ donor (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain in extremity (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiration abnormal (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Snoring (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Trismus (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3628** | click or scan EU-EC-10009711172 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Intestinal obstruction (64d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urinary tract infection (64d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Vomiting (64d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3629** | click or scan EU-EC-10009711160 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (36d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abortion spontaneous (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Congenital Anomaly) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3630** | click or scan EU-EC-10009711114 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (1d - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Endotracheal intubation (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3631** | click or scan EU-EC-10009710765 | | 2021-08-17 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Azotaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperlactacidaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Personality change (n/a - Recovered/Resolved - ), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3632** | click or scan EU-EC-10009710599 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **3633** | click or scan EU-EC-10009710584 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Portal vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 2 {DF} - Intramuscular]) |
| **3634** | click or scan EU-EC-10009710578 | | 2021-08-17 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **3635** | click or scan EU-EC-10009710385 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Blood pressure decreased (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cholelithiasis (n/a - Fatal - **Results in Death**), Coma scale abnormal (n/a - Fatal - **Results in Death**), Diverticulum intestinal (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Fatal - **Results in Death**), Feeding disorder (n/a - Fatal - **Results in Death**), Fibrinolysis increased (n/a - Fatal - **Results in Death**), Haematochezia (n/a - Fatal - **Results in Death**), Heart rate decreased (n/a - Fatal - **Results in Death**), Hyperhidrosis (n/a - Fatal - **Results in Death**), Intestinal dilatation (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3636** | click or scan EU-EC-10009710100 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - ), Embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3637** | click or scan EU-EC-10009709960 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3638** | click or scan EU-EC-10009709697 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3639** | click or scan EU-EC-10009709663 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3640** | click or scan EU-EC-10009709233 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Acute myocardial infarction (1d - Fatal - **Results in Death**), Cardiac arrest (1d - Fatal - **Results in Death**), Dyspnoea (3d - Fatal - **Results in Death**), Haemoptysis (3d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **3641** | click or scan EU-EC-10009709175 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (6d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |
| **3642** | click or scan EU-EC-10009709021 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cold sweat (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3643** | click or scan EU-EC-10009708594 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dysphonia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hiccups (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Unknown]) |
| **3644** | click or scan EU-EC-10009708478 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Vaccination site swelling (n/a - Recovered/Resolved - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3645** | click or scan EU-EC-10009708429 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinusitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3646** | click or scan EU-EC-10009708304 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3647** | click or scan EU-EC-10009708249 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3648** | click or scan EU-EC-10009708204 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3649** | click or scan EU-EC-10009708168 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **3650** | click or scan EU-EC-10009707799 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Language disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3651** | click or scan EU-EC-10009707796 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral infarction (5d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3652** | click or scan EU-EC-10009707795 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **3653** | click or scan EU-EC-10009707794 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3654** | click or scan EU-EC-10009707783 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute hepatic failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Acute myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Aortic stenosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain hypoxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lactic acidosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rash (n/a - Fatal - **Results in Death**), Rash erythematous (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Rheumatoid arthritis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3655** | click or scan EU-EC-10009707772 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin lesion (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3656** | click or scan EU-EC-10009707747 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3657** | click or scan EU-EC-10009707675 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **3658** | click or scan EU-EC-10009707610 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3659** | click or scan EU-EC-10009707106 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3660** | click or scan EU-EC-10009706809 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3661** | click or scan EU-EC-10009706690 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chills (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**), Vaccination site pain (2d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3662** | click or scan EU-EC-10009706625 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3663** | click or scan EU-EC-10009706618 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure decreased (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Unevaluable event (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3664** | click or scan EU-EC-10009706617 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Blood pressure increased (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3665** | click or scan EU-EC-10009706584 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3666** | click or scan EU-EC-10009706576 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3667** | click or scan EU-EC-10009706466 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3668** | click or scan EU-EC-10009706464 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3669** | click or scan EU-EC-10009706413 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3670** | click or scan EU-EC-10009706412 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Female | Hypersensitivity (4d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3671** | click or scan EU-EC-10009706383 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3672** | click or scan EU-EC-10009706376 | | 2021-08-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3673** | click or scan EU-EC-10009706370 | | 2021-08-17 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3674** | click or scan EU-EC-10009706325 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3675** | click or scan EU-EC-10009706323 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drowning (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3676** | click or scan EU-EC-10009706174 | | 2021-08-17 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3677** | click or scan EU-EC-10009706142 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3678** | click or scan EU-EC-10009705979 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3679** | click or scan EU-EC-10009705914 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3680** | click or scan EU-EC-10009705694 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3681** | click or scan EU-EC-10009705642 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3682** | click or scan EU-EC-10009705615 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Gastrointestinal haemorrhage (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3683** | click or scan EU-EC-10009705614 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (2d - Fatal - **Results in Death**, Other Medically Important Condition), Fall (1d - Recovered/Resolved - ), Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (2d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1min - 1 {DF} - Intramuscular]) |
| **3684** | click or scan EU-EC-10009705479 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3685** | click or scan EU-EC-10009705180 | | 2021-08-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3686** | click or scan EU-EC-10009705161 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aggression (n/a - Unknown - ), Cellulitis (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3687** | click or scan EU-EC-10009705144 | | 2021-08-17 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3688** | click or scan EU-EC-10009705093 | | 2021-08-17 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3689** | click or scan EU-EC-10009704447 | | 2021-08-17 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3690** | click or scan EU-EC-10009704289 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arterial thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Carotid artery thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular accident (3d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebrovascular insufficiency (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gastrointestinal sounds abnormal (n/a - Unknown - ), Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypertension (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - ), Platelet disorder (n/a - Unknown - Other Medically Important Condition), Pupil fixed (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupillary reflex impaired (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3691** | click or scan EU-EC-10009703982 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3692** | click or scan EU-EC-10009703789 | | 2021-08-17 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (26d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3693** | click or scan EU-EC-10009703522 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung consolidation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia pneumococcal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3694** | click or scan EU-EC-10009702880 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrooesophageal reflux disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3695** | click or scan EU-EC-10009702873 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3696** | click or scan EU-EC-10009702750 | | 2021-08-17 | Non Healthcare Professional | Non EEA | Not Specified | Male | Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3697** | click or scan EU-EC-10009702686 | | 2021-08-17 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Apnoea (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3698** | click or scan EU-EC-10009702648 | | 2021-08-17 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (0d - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **3699** | click or scan EU-EC-10009702054 | | 2021-08-17 | Non Healthcare Professional | EEA | More than 85 Years | Male | Coma (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3700** | click or scan EU-EC-10009701831 | | 2021-08-17 | Non Healthcare Professional | EEA | 18-64 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3701** | click or scan EU-EC-10009700642 | | 2021-08-17 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest pain (66d - Fatal - **Results in Death**), Pneumonia (66d - Fatal - **Results in Death**), Thrombosis (66d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **3702** | click or scan EU-EC-10009701686 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (106d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain neoplasm (87d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neoplasm malignant (87d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3703** | click or scan EU-EC-10009701467 | | 2021-08-16 | Non Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3704** | click or scan EU-EC-10009701420 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3705** | click or scan EU-EC-10009701419 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Metabolic encephalopathy (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (22d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3706** | click or scan EU-EC-10009701348 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (1d - Fatal - **Results in Death**), Diabetes mellitus inadequate control (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3707** | click or scan EU-EC-10009701335 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3708** | click or scan EU-EC-10009701171 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3709** | click or scan EU-EC-10009701033 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Contusion (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vascular dementia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3710** | click or scan EU-EC-10009700803 | | 2021-08-16 | Healthcare Professional | Non EEA | Not Specified | Male | Cerebral haematoma (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Chills (n/a - Recovering/Resolving - ), Haematoma (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Pain (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3711** | click or scan EU-EC-10009700049 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3712** | click or scan EU-EC-10009699810 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Recovered/Resolved - ), Dyspnoea (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3713** | click or scan EU-EC-10009699772 | | 2021-08-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Lung neoplasm malignant (n/a - Fatal - **Results in Death**), Neoplasm progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3714** | click or scan EU-EC-10009699437 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Ascites (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**), Petechiae (n/a - Fatal - **Results in Death**), Pharyngeal oedema (n/a - Fatal - **Results in Death**), Pleural effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3715** | click or scan EU-EC-10009699296 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abdominal pain (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3716** | click or scan EU-EC-10009699123 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3717** | click or scan EU-EC-10009698859 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3718** | click or scan EU-EC-10009698852 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening), Death (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3719** | click or scan EU-EC-10009698838 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3720** | click or scan EU-EC-10009698821 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3721** | click or scan EU-EC-10009698717 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3722** | click or scan EU-EC-10009698712 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Gastrooesophageal reflux disease (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3723** | click or scan EU-EC-10009698667 | | 2021-08-16 | Healthcare Professional | EEA | Not Specified | Female | Anuria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) |
| **3724** | click or scan EU-EC-10009698587 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3725** | click or scan EU-EC-10009698586 | | 2021-08-16 | Non Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Pain (n/a - Not Recovered/Not Resolved - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [1d - 1{DF} - n/a]) |
| **3726** | click or scan EU-EC-10009698580 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3727** | click or scan EU-EC-10009698536 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3728** | click or scan EU-EC-10009698526 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [29d - 1{DF} - Intramuscular]) |
| **3729** | click or scan EU-EC-10009698495 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3730** | click or scan EU-EC-10009698460 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Rhabdomyolysis (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3731** | click or scan EU-EC-10009698394 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3732** | click or scan EU-EC-10009698369 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3733** | click or scan EU-EC-10009698208 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3734** | click or scan EU-EC-10009698149 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3735** | click or scan EU-EC-10009697793 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Urinary tract infection (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3736** | click or scan EU-EC-10009697787 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3737** | click or scan EU-EC-10009697770 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3738** | click or scan EU-EC-10009697734 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3739** | click or scan EU-EC-10009697727 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3740** | click or scan EU-EC-10009697714 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3741** | click or scan EU-EC-10009697649 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic reaction (6h - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3742** | click or scan EU-EC-10009697326 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3743** | click or scan EU-EC-10009696643 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3744** | click or scan EU-EC-10009696627 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening), Cardiac hypertrophy (n/a - Fatal - **Results in Death**, Life Threatening), Cardiomegaly (n/a - Fatal - **Results in Death**, Life Threatening), Cholelithiasis (n/a - Fatal - **Results in Death**, Life Threatening), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening), Obesity (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary oedema (n/a - Fatal - **Results in Death**, Life Threatening), Renal cyst (n/a - Fatal - **Results in Death**, Life Threatening), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) DISPERSION FOR INJECTION [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Prophylaxis - n/a - [n/a - .5mL - Intramuscular]) |
| **3745** | click or scan EU-EC-10009696571 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Fluid retention (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3746** | click or scan EU-EC-10009696550 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3747** | click or scan EU-EC-10009696407 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3748** | click or scan EU-EC-10009696068 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3749** | click or scan EU-EC-10009695609 | | 2021-08-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Bladder disorder (n/a - Unknown - ), Cough (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Prostatic disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3750** | click or scan EU-EC-10009695559 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Hypoglycaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Presyncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3751** | click or scan EU-EC-10009695548 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3752** | click or scan EU-EC-10009695547 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Multiple system atrophy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3753** | click or scan EU-EC-10009695537 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3754** | click or scan EU-EC-10009695498 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Wheezing (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3755** | click or scan EU-EC-10009695446 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3756** | click or scan EU-EC-10009695392 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiplegia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count abnormal (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **3757** | click or scan EU-EC-10009695365 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (5d - Unknown - Life Threatening), Chills (5d - Unknown - Life Threatening), Death (5d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (5d - Unknown - Life Threatening), Pain (5d - Unknown - Life Threatening), Pyrexia (5d - Unknown - Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3758** | click or scan EU-EC-10009694713 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Female | Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3759** | click or scan EU-EC-10009694525 | | 2021-08-16 | Healthcare Professional | Non EEA | Not Specified | Female | Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3760** | click or scan EU-EC-10009694448 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3761** | click or scan<br>EU-EC-10009694063 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Angina pectoris (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3762** | click or scan<br>EU-EC-10009694045 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3763** | click or scan<br>EU-EC-10009693673 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aphonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Areflexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Blood sodium decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Constipation (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hilar lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Retroperitoneal lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sensory loss (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Splenomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3764** | click or scan<br>EU-EC-10009693665 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Inappropriate schedule of product administration (n/a - Unknown - ), Small for dates baby (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **3765** | click or scan<br>EU-EC-10009693146 | | 2021-08-16 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **3766** | click or scan<br>EU-EC-10009693143 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Insomnia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3767** | click or scan<br>EU-EC-10009693111 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3768** | click or scan EU-EC-10009693099 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle twitching (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle twitching (n/a - Unknown - ), Off label use (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Skull fracture (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Traumatic haemorrhage (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3769** | click or scan EU-EC-10009693090 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3770** | click or scan EU-EC-10009693076 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3771** | click or scan EU-EC-10009693062 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3772** | click or scan EU-EC-10009693053 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Hallucination (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3773** | click or scan EU-EC-10009692178 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3774** | click or scan EU-EC-10009692176 | | 2021-08-16 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Anosmia (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Subdural haematoma (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3775** | click or scan EU-EC-10009692157 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3776** | click or scan EU-EC-10009691764 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3777** | click or scan EU-EC-10009691755 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3778** | click or scan EU-EC-10009691740 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3779** | click or scan EU-EC-10009691594 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3780** | click or scan EU-EC-10009691550 | | 2021-08-16 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**), Myocardial infarction (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3781** | click or scan EU-EC-10009691510 | | 2021-08-16 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Pain (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3782** | click or scan EU-EC-10009691431 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Female | Azotaemia (n/a - Fatal - **Results in Death**), Hydrocephalus (n/a - Fatal - **Results in Death**), Intracranial pressure increased (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3783** | click or scan EU-EC-10009691422 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arrhythmia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3784** | click or scan EU-EC-10009691327 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3785** | click or scan EU-EC-10009691325 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic rupture (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **3786** | click or scan EU-EC-10009691140 | | 2021-08-16 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (9d - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Coagulopathy (9d - Fatal - **Results in Death**, Other Medically Important Condition), Epistaxis (n/a - Unknown - ), Haematoma (n/a - Unknown - Other Medically Important Condition), Haemorrhage (n/a - Unknown - ), Headache (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Paraparesis (n/a - Unknown - Other Medically Important Condition), Puncture site haemorrhage (n/a - Unknown - Other Medically Important Condition), Pupils unequal (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Quadriplegia (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3787** | click or scan EU-EC-10009691124 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3788** | click or scan EU-EC-10009691104 | | 2021-08-16 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3789** | click or scan EU-EC-10009690933 | | 2021-08-16 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Bradycardia (n/a - Unknown - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hyporesponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Presyncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3790** | click or scan EU-EC-10009690812 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3791** | click or scan EU-EC-10009690789 | | 2021-08-16 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3792** | click or scan EU-EC-10009688843 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Abnormal loss of weight (n/a - Not Recovered/Not Resolved - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Chromaturia (n/a - Not Recovered/Not Resolved - **Results in Death**), Cough (n/a - Not Recovered/Not Resolved - **Results in Death**), Decreased appetite (n/a - Not Recovered/Not Resolved - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Epstein-Barr virus infection (n/a - Not Recovered/Not Resolved - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - **Results in Death**), Haemophagocytic lymphohistiocytosis (n/a - Not Recovered/Not Resolved - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Insomnia (n/a - Not Recovered/Not Resolved - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - **Results in Death**), Rheumatoid arthritis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3793** | click or scan EU-EC-10009688842 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**), Chest pain (n/a - Not Recovered/Not Resolved - **Results in Death**), Ventricular hypertrophy (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **3794** | click or scan EU-EC-10009688835 | | 2021-08-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Anisocytosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), End stage renal disease (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Fluid overload (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell elliptocytes present (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell morphology abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell target cells present (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Rouleaux formation (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3795** | click or scan EU-EC-10009688826 | | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac valve disease (n/a - Not Recovered/Not Resolved - **Results in Death**), Encephalitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Malaise (n/a - Unknown - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3796** | click or scan EU-EC-10009688716 | | 2021-08-14 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Renal pain (n/a - Unknown - **Results in Death**), Sleep disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3797** | click or scan EU-EC-10009688660 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Male | Deep vein thrombosis (7d - Not Recovered/Not Resolved - **Results in Death**), Diarrhoea (1wk - Not Recovered/Not Resolved - **Results in Death**), Pain in extremity (1wk - Not Recovered/Not Resolved - **Results in Death**), Pulmonary embolism (7d - Fatal - **Results in Death**), Renal infarct (n/a - Not Recovered/Not Resolved - **Results in Death**), Splenic infarction (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]) |
| **3798** | click or scan EU-EC-10009688656 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**), Cerebrovascular accident (8d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3799** | click or scan EU-EC-10009688350 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myeloid leukaemia (69d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **3800** | click or scan EU-EC-10009688336 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Haemophagocytic lymphohistiocytosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemophagocytic lymphohistiocytosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Sepsis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **3801** | click or scan EU-EC-10009688325 | | 2021-08-14 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Unknown - **Results in Death**), Cardiac arrest (n/a - Unknown - **Results in Death**), Chest pain (n/a - Unknown - **Results in Death**), Coronary artery thrombosis (3d - Fatal - **Results in Death**), Ischaemia (n/a - Unknown - **Results in Death**), Rectal haemorrhage (n/a - Unknown - **Results in Death**), Shock (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Unknown - **Results in Death**), Thrombosis mesenteric vessel (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3802** | click or scan EU-EC-10009688163 | | 2021-08-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (31d - Not Recovered/Not Resolved - **Results in Death**), Death (2527d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **3803** | click or scan EU-EC-10009687983 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **3804** | click or scan EU-EC-10009687484 | | 2021-08-14 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (2d - Recovered/Resolved - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (2d - Recovered/Resolved - ), Diarrhoea (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Pain in extremity (2d - Recovered/Resolved - ), Vomiting (2d - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **3805** | click or scan EU-EC-10009687338 | | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Atelectasis (1d - Fatal - **Results in Death**), Cardiomegaly (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Lung opacity (1d - Fatal - **Results in Death**), Oedema (1d - Fatal - **Results in Death**), Pleural effusion (1d - Fatal - **Results in Death**), Pneumonia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3806** | click or scan<br>EU-EC-10009687321 | | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3807** | click or scan<br>EU-EC-10009687315 | | 2021-08-14 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain lower (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Back pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Febrile neutropenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Illness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Non-Hodgkin's lymphoma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3808** | click or scan<br>EU-EC-10009687310 | | 2021-08-14 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Axillary pain (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Bladder hypertrophy (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Condition aggravated (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Confusional state (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Herpes zoster (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Injection site mass (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Lung disorder (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Lymphadenectomy (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Mental status changes (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Oedema (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Pain in extremity (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Pulmonary artery dilatation (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary hypertension (n/a - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary mass (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Retroperitoneal lymphadenopathy (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Splenic lesion (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Tenderness (n/a - Fatal - **Results in Death**, Life Threatening, Disabling), Urinary tract infection (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3809** | click or scan<br>EU-EC-10009687268 | | 2021-08-14 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subarachnoid haemorrhage (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subdural haematoma (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **3810** | click or scan<br>EU-EC-10009687149 | | 2021-08-14 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Cardiac failure (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **3811** | click or scan<br>EU-EC-10009686455 | | 2021-08-14 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3812** | click or scan<br>EU-EC-10009685890 | | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (7d - Unknown - Caused/Prolonged Hospitalisation), Chills (7d - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (7d - Unknown - Caused/Prolonged Hospitalisation), Headache (7d - Unknown - Caused/Prolonged Hospitalisation), Intestinal obstruction (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (7d - Unknown - Caused/Prolonged Hospitalisation), Nervousness (7d - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - ), Pyrexia (7d - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3813** | click or scan EU-EC-10009685820 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary haemorrhage (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3814** | click or scan EU-EC-10009685419 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| **3815** | click or scan EU-EC-10009685165 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Apnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoxia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oedema (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sputum increased (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3816** | click or scan EU-EC-10009684820 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3817** | click or scan EU-EC-10009684641 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Drug reaction with eosinophilia and systemic symptoms (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3818** | click or scan EU-EC-10009684628 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3819** | click or scan EU-EC-10009684578 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Taste disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3820** | click or scan EU-EC-10009684012 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paresis (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3821** | click or scan EU-EC-10009683705 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3822** | click or scan EU-EC-10009683184 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3823 | click or scan EU-EC-10009683100 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3824 | click or scan EU-EC-10009682146 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiomegaly (n/a - Fatal - **Results in Death**), Congestive hepatopathy (n/a - Fatal - **Results in Death**), Kidney congestion (n/a - Fatal - **Results in Death**), Pulmonary congestion (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| 3825 | click or scan EU-EC-10009682135 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hemiparesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| 3826 | click or scan EU-EC-10009682081 | | 2021-08-13 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (4d - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1{DF} - Intramuscular]) |
| 3827 | click or scan EU-EC-10009682062 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (24h - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) |
| 3828 | click or scan EU-EC-10009681986 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 3829 | click or scan EU-EC-10009681956 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| 3830 | click or scan EU-EC-10009681890 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| 3831 | click or scan EU-EC-10009681826 | | 2021-08-13 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | B-cell lymphoma (n/a - Fatal - **Results in Death**), Haematopoietic neoplasm (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| 3832 | click or scan EU-EC-10009681701 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Pancreatitis acute (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3833** | click or scan EU-EC-10009681611 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Congestive cardiomyopathy (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3834** | click or scan EU-EC-10009681609 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Emphysema (n/a - Fatal - **Results in Death**), Pulmonary fibrosis (n/a - Fatal - **Results in Death**), Pulmonary hypertension (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3835** | click or scan EU-EC-10009681021 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arterial thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ischaemic stroke (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular]) |
| **3836** | click or scan EU-EC-10009680970 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Aortic rupture (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3837** | click or scan EU-EC-10009680877 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **3838** | click or scan EU-EC-10009680855 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Loss of consciousness (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**), Seizure (0d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3839** | click or scan EU-EC-10009680850 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening), Neurodegenerative disorder (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Paralysis (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Swelling (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3840** | click or scan EU-EC-10009680661 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), DARATUMUMAB [DARATUMUMAB] (S - Plasma cell myeloma - Not applicable - [n/a - n/a - n/a]), REVLIMID [LENALIDOMIDE] (S - Plasma cell myeloma - Not applicable - [n/a - n/a - n/a]) |
| **3841** | click or scan EU-EC-10009680612 | | 2021-08-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Chills (21d - Fatal - **Results in Death**), Death (21d - Fatal - **Results in Death**), Fatigue (21d - Fatal - **Results in Death**), Malaise (21d - Fatal - **Results in Death**), Nausea (21d - Fatal - **Results in Death**), Pyrexia (21d - Fatal - **Results in Death**), Respiratory failure (21d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3842** | click or scan EU-EC-10009680506 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular disorder (0d - Fatal - **Results in Death**), Circulatory collapse (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3843** | click or scan EU-EC-10009680395 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3844** | click or scan EU-EC-10009680330 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3845** | click or scan EU-EC-10009679774 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3846** | click or scan EU-EC-10009679665 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3847** | click or scan EU-EC-10009679578 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3848** | click or scan EU-EC-10009679577 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **3849** | click or scan EU-EC-10009679572 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac dysfunction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3850** | click or scan EU-EC-10009679255 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Unevaluable event (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| **3851** | click or scan EU-EC-10009679194 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Neuralgic amyotrophy (n/a - Fatal - **Results in Death**, Disabling), Paralysis (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **3852** | click or scan EU-EC-10009679174 | | 2021-08-13 | Non Healthcare Professional | EEA | More than 85 Years | Male | Ischaemic stroke (0d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3853** | click or scan EU-EC-10009679000 | | 2021-08-13 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Inappropriate schedule of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3854** | click or scan EU-EC-10009678974 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3855** | click or scan EU-EC-10009678913 | | 2021-08-13 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (17d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3856** | click or scan EU-EC-10009678898 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Unevaluable event (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **3857** | click or scan EU-EC-10009678840 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (53d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3858** | click or scan EU-EC-10009678740 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3859** | click or scan EU-EC-10009678594 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 pneumonia (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Decreased appetite (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dehydration (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (89d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **3860** | click or scan EU-EC-10009678492 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (7d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3861** | click or scan EU-EC-10009678473 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Death (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **3862** | click or scan EU-EC-10009678396 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3863** | click or scan EU-EC-10009678390 | | 2021-08-13 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cellulitis (n/a - Fatal - **Results in Death**), Chills (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sepsis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3864** | click or scan EU-EC-10009678215 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3865** | click or scan EU-EC-10009678163 | | 2021-08-13 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3866** | click or scan EU-EC-10009678136 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dizziness (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3867** | click or scan EU-EC-10009677966 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic dissection (2d - Fatal - **Results in Death**), Back pain (2d - Fatal - **Results in Death**), Cardiovascular disorder (2d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diplegia (1d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Monoplegia (1d - Fatal - **Results in Death**), Renal failure (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3868** | click or scan EU-EC-10009677767 | | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (39990min - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchospasm (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (28d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sneezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Taste disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3869** | click or scan EU-EC-10009677762 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3870** | click or scan EU-EC-10009677441 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3871** | click or scan EU-EC-10009677360 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Male | Leukoencephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **3872** | click or scan EU-EC-10009677335 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**), Blood fibrinogen increased (n/a - Fatal - **Results in Death**), Brain oedema (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral ischaemia (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**), Limb discomfort (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**), Retrograde amnesia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Snoring (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Superior sagittal sinus thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3873** | click or scan EU-EC-10009677105 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [5s - 1{DF} - Intramuscular]) |
| **3874** | click or scan EU-EC-10009676982 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (2d - Fatal - **Results in Death**), Death (2d - Fatal - **Results in Death**), Nervous system disorder (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3875** | click or scan EU-EC-10009676937 | | 2021-08-13 | Non Healthcare Professional | EEA | More than 85 Years | Female | Blindness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Delusion (n/a - Not Recovered/Not Resolved - ), Dysphagia (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscle spasms (1wk - Recovered/Resolved - Caused/Prolonged Hospitalisation), Panic attack (n/a - Not Recovered/Not Resolved - ), Status epilepticus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **3876** | click or scan EU-EC-10009676897 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Facial asymmetry (n/a - Unknown - ), Facial spasm (n/a - Unknown - ), Hypotension (1d - Recovered/Resolved - ), Somnolence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3877** | click or scan EU-EC-10009676863 | | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Male | Carditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3878** | click or scan EU-EC-10009676535 | | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (3d - Unknown - ), Pyrexia (3d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3879** | click or scan EU-EC-10009676509 | | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Thrombotic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3880** | click or scan EU-EC-10009676501 | | 2021-08-13 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Oesophageal carcinoma (n/a - Unknown - Other Medically Important Condition), Paralysis (n/a - Unknown - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3881** | click or scan EU-EC-10009676372 | | 2021-08-13 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Headache (1d - Fatal - **Results in Death**), Nervous system disorder (1d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3882** | click or scan EU-EC-10009676127 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Female | Malaise (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3883** | click or scan EU-EC-10009676112 | | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Female | Headache (9d - Fatal - **Results in Death**), Subarachnoid haemorrhage (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3884** | click or scan EU-EC-10009676103 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Septic shock (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| **3885** | click or scan EU-EC-10009676017 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Oral fungal infection (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory moniliasis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superinfection bacterial (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **3886** | click or scan EU-EC-10009676014 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (1d - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Pulmonary pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3887** | click or scan EU-EC-10009675970 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3888** | click or scan EU-EC-10009675693 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3889** | click or scan EU-EC-10009675680 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Not Recovered/Not Resolved - ), Interstitial lung disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3890** | click or scan EU-EC-10009675605 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Fall (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3891** | click or scan EU-EC-10009675595 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3892** | click or scan EU-EC-10009675474 | | 2021-08-13 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **3893** | click or scan EU-EC-10009675468 | | 2021-08-13 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**), Cerebral haematoma (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Haemorrhage (n/a - Fatal - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Fatal - **Results in Death**), Mesenteric vein thrombosis (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pneumothorax (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Renal infarct (n/a - Fatal - **Results in Death**), Renal vein thrombosis (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Splenic infarction (n/a - Fatal - **Results in Death**), Splenic vein thrombosis (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Venous occlusion (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3894** | click or scan EU-EC-10009675319 | | 2021-08-13 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chills (17d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (17d - Fatal - **Results in Death**), Headache (17d - Fatal - **Results in Death**), Malaise (17d - Fatal - **Results in Death**), Myalgia (17d - Fatal - **Results in Death**), Nausea (17d - Fatal - **Results in Death**), Pyrexia (17d - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3895** | click or scan EU-EC-10009674824 | | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Leukaemia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3896** | click or scan EU-EC-10009674822 | | 2021-08-13 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Nipple pain (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3897** | click or scan EU-EC-10009674751 | | 2021-08-13 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Brain death (2wk - Fatal - **Results in Death**), Cerebral venous thrombosis (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - ), Vision blurred (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3898** | click or scan EU-EC-10009674295 | | 2021-08-13 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (79d - Fatal - **Results in Death**), Loss of consciousness (79d - Fatal - **Results in Death**), Peripheral swelling (79d - Fatal - **Results in Death**), Pyrexia (79d - Fatal - **Results in Death**), Tremor (79d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **3899** | click or scan EU-EC-10009674256 | | 2021-08-13 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3900** | click or scan EU-EC-10009673553 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (1d - Unknown - ), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3901** | click or scan EU-EC-10009673385 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure acute (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (0d - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular]) |
| **3902** | click or scan EU-EC-10009673133 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiogenic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (22d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 100ug - Intramuscular]) |
| **3903** | click or scan EU-EC-10009672980 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Myocardial infarction (2h - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 100ug - Intramuscular - More in ICSR]) |
| **3904** | click or scan EU-EC-10009672260 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3905** | click or scan EU-EC-10009672256 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (2d - Fatal - **Results in Death**), Fatigue (2d - Fatal - **Results in Death**), Pain (2d - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3906** | click or scan EU-EC-10009672254 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3907** | click or scan EU-EC-10009672229 | | 2021-08-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Coronary artery disease (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3908** | click or scan EU-EC-10009671307 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3909** | click or scan EU-EC-10009671154 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]), [SUMATRIPTAN] (S - Migraine - Unknown - [n/a - 100mg - Oral]) |
| **3910** | click or scan EU-EC-10009670757 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (2d - Fatal - **Results in Death**), Embolic stroke (2d - Fatal - **Results in Death**), Embolism venous (2d - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Unknown - **Results in Death**), Pulmonary embolism (2d - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3911** | click or scan EU-EC-10009670682 | | 2021-08-12 | Non Healthcare Professional | EEA | Not Specified | Male | Malaise (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **3912** | click or scan EU-EC-10009670579 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Atypical pneumonia (n/a - Unknown - Other Medically Important Condition), Blood pressure increased (n/a - Unknown - ), C-reactive protein increased (n/a - Unknown - ), Dehydration (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Unknown - ), Lung infiltration (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3913** | click or scan EU-EC-10009670445 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]), FILGRASTIM [FILGRASTIM] (S - Haematopoietic stem cell mobilisation - Not applicable - [4d - 600ug - Unknown]) |
| **3914** | click or scan EU-EC-10009670051 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [29d - 1 {DF} - Intramuscular - More in ICSR]) |
| **3915** | click or scan EU-EC-10009670009 | | 2021-08-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **3916** | click or scan EU-EC-10009669573 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Bacterial sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3917** | click or scan EU-EC-10009669340 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) |
| **3918** | click or scan EU-EC-10009668410 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [43d - 2 {DF} - Intramuscular]) |
| **3919** | click or scan EU-EC-10009668394 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3920** | click or scan EU-EC-10009668300 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Systemic lupus erythematosus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [22d - 2 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3921** | click or scan EU-EC-10009668223 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **3922** | click or scan EU-EC-10009668028 | | 2021-08-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3923** | click or scan EU-EC-10009668005 | | 2021-08-12 | Non Healthcare Professional | Non EEA | Not Specified | Female | Cerebral thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3924** | click or scan EU-EC-10009667788 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3925** | click or scan EU-EC-10009666774 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bacterial sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Fibrin D dimer increased (n/a - Unknown - ), Heart rate increased (n/a - Unknown - ), Hypotension (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - ), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Procalcitonin increased (n/a - Unknown - ), Pulmonary sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - ), Respiratory acidosis (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Septic shock (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **3926** | click or scan EU-EC-10009666762 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3927** | click or scan EU-EC-10009666762 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interchange of vaccine products (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3928** | click or scan EU-EC-10009666750 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3929** | click or scan EU-EC-10009666744 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3930** | click or scan EU-EC-10009666738 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Agitation (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Cyanosis (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dysphagia (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3931** | click or scan EU-EC-10009666487 | | 2021-08-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Musculoskeletal disorder (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **3932** | click or scan EU-EC-10009666290 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3933** | click or scan EU-EC-10009666271 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3934** | click or scan EU-EC-10009666267 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vision blurred (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **3935** | click or scan EU-EC-10009666164 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Blister (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), Renal failure (n/a - Fatal - **Results in Death**), Skin weeping (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **3936** | click or scan EU-EC-10009665794 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Oesophageal varices haemorrhage (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3937** | click or scan EU-EC-10009665764 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**), Concomitant disease progression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3938** | click or scan EU-EC-10009665394 | | 2021-08-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3939** | click or scan EU-EC-10009665383 | | 2021-08-12 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3940** | click or scan EU-EC-10009665359 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3941** | click or scan EU-EC-10009665127 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Not Recovered/Not Resolved - ), Muscular weakness (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **3942** | click or scan EU-EC-10009665043 | | 2021-08-12 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiopulmonary failure (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Resuscitation (n/a - Fatal - **Results in Death**) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **3943** | click or scan EU-EC-10009665011 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**), Influenza like illness (1d - Fatal - **Results in Death**), Respiratory distress (1d - Fatal - **Results in Death**), Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3944** | click or scan EU-EC-10009664894 | | 2021-08-12 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3945** | click or scan EU-EC-10009664893 | | 2021-08-12 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **3946** | click or scan EU-EC-10009664710 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3947** | click or scan EU-EC-10009664549 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**), Fibrin D dimer increased (1d - Fatal - **Results in Death**), Leukocytosis (1d - Fatal - **Results in Death**), Neutrophilia (1d - Fatal - **Results in Death**), Oxygen saturation decreased (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (1d - Fatal - **Results in Death**), Urinary tract infection (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3948** | click or scan EU-EC-10009664203 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3949** | click or scan EU-EC-10009664192 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac flutter (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| 3950 | click or scan EU-EC-10009664188 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3951 | click or scan EU-EC-10009664107 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain oedema (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intraventricular haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Monoparesis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Photophobia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Testicular pain (n/a - Recovering/Resolving - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| 3952 | click or scan EU-EC-10009663719 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| 3953 | click or scan EU-EC-10009663700 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Injection site haematoma (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| 3954 | click or scan EU-EC-10009663278 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Acute abdomen (4d - Fatal - **Results in Death**), Acute myocardial infarction (4d - Fatal - **Results in Death**), Cerebral infarction (4d - Fatal - **Results in Death**), Intestinal ischaemia (4d - Fatal - **Results in Death**), Mesenteric artery stent insertion (4d - Fatal - **Results in Death**), Pupils unequal (4d - Fatal - **Results in Death**), Renal infarct (4d - Fatal - **Results in Death**), Shock (4d - Fatal - **Results in Death**), Splenic infarction (4d - Fatal - **Results in Death**), Thrombectomy (4d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| 3955 | click or scan EU-EC-10009663046 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| 3956 | click or scan EU-EC-10009663041 | | 2021-08-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Agitation (n/a - Fatal - **Results in Death**), Angioedema (n/a - Fatal - **Results in Death**), Anxiety (n/a - Fatal - **Results in Death**), Bronchospasm (n/a - Fatal - **Results in Death**), Chest discomfort (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Feeling of body temperature change (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Mouth ulceration (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Rash (n/a - Fatal - **Results in Death**), Urticaria (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| 3957 | click or scan EU-EC-10009663036 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3958** | click or scan EU-EC-10009663033 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3959** | click or scan EU-EC-10009663027 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3960** | click or scan EU-EC-10009662582 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3961** | click or scan EU-EC-10009662571 | | 2021-08-12 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3962** | click or scan EU-EC-10009662567 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dizziness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3963** | click or scan EU-EC-10009662563 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | General physical health deterioration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Respiratory disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3964** | click or scan EU-EC-10009662562 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased activity (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3965** | click or scan EU-EC-10009662561 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3966** | click or scan EU-EC-10009662557 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Brain injury (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Lung consolidation (n/a - Unknown - Other Medically Important Condition), Post cardiac arrest syndrome (n/a - Fatal - **Results in Death**), Rib fracture (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3967** | click or scan EU-EC-10009662550 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3968** | click or scan EU-EC-10009662548 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3969** | click or scan EU-EC-10009662536 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Intestinal ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3970** | click or scan EU-EC-10009662319 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cardiovascular disorder (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Injection site discomfort (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3971** | click or scan EU-EC-10009661935 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3972** | click or scan EU-EC-10009661745 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebellar infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eye movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3973** | click or scan EU-EC-10009661635 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Pancytopenia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **3974** | click or scan EU-EC-10009661629 | | 2021-08-12 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cholelithiasis (n/a - Unknown - ), Dysphonia (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3975** | click or scan EU-EC-10009661627 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3976** | click or scan EU-EC-10009661626 | | 2021-08-12 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Coagulopathy (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **3977** | click or scan EU-EC-10009661612 | | 2021-08-12 | Healthcare Professional | Non EEA | 65-85 Years | Female | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **3978** | click or scan EU-EC-10009661601 | | 2021-08-12 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain herniation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3979** | click or scan EU-EC-10009661466 | | 2021-08-12 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coagulopathy (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Night sweats (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Red blood cell count increased (n/a - Unknown - Other Medically Important Condition), White blood cell count increased (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3980** | click or scan EU-EC-10009661072 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Ascites (54d - Fatal - **Results in Death**), Metastases to liver (54d - Fatal - **Results in Death**), Metastases to lung (54d - Fatal - **Results in Death**), Metastases to lymph nodes (54d - Fatal - **Results in Death**), Metastases to the mediastinum (54d - Fatal - **Results in Death**), Pancreatic carcinoma (54d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| **3981** | click or scan EU-EC-10009660858 | | 2021-08-12 | Healthcare Professional | EEA | More than 85 Years | Female | Unresponsive to stimuli (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **3982** | click or scan EU-EC-10009660857 | | 2021-08-12 | Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haematoma (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **3983** | click or scan EU-EC-10009660838 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (18d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3984** | click or scan EU-EC-10009660814 | | 2021-08-12 | Healthcare Professional | EEA | 65-85 Years | Female | Back pain (0d - Fatal - **Results in Death**), Hyperthermia (0d - Fatal - **Results in Death**), Pain in extremity (0d - Fatal - **Results in Death**), Terminal state (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **3985** | click or scan EU-EC-10009660511 | | 2021-08-11 | Healthcare Professional | EEA | 18-64 Years | Female | Aphasia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhagic cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemianaesthesia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - ), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]), [DYDROGESTERONE] (S - Ovarian cyst - n/a - [1d - 10mg - Oral]), [ESTRADIOL HEMIHYDRATE, ESTRADIOL VALERATE] (S - Ovarian cyst - Not applicable - [1d - 2mg - Oral]) |
| **3986** | click or scan EU-EC-10009659137 | | 2021-08-11 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal growth restriction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]) |
| **3987** | click or scan EU-EC-10009659037 | | 2021-08-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3988** | click or scan EU-EC-10009658476 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Male | Bradykinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cognitive disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **3989** | click or scan EU-EC-10009657404 | | 2021-08-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (1d - Fatal - **Results in Death**, Other Medically Important Condition), Diarrhoea (5d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ), Malaise (5d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (8d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (5d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3990** | click or scan EU-EC-10009657250 | | 2021-08-11 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral venous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhagic transformation stroke (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Other Medically Important Condition), Intracranial pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **3991** | click or scan EU-EC-10009657248 | | 2021-08-11 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **3992** | click or scan EU-EC-10009657239 | | 2021-08-11 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **3993** | click or scan EU-EC-10009656345 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Disseminated intravascular coagulation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Portal vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Transient ischaemic attack - Drug withdrawn - [n/a - 1{DF} - Oral]) |
| **3994** | click or scan EU-EC-10009656316 | | 2021-08-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Hepatic vein thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Parenteral]) |
| **3995** | click or scan EU-EC-10009656310 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intradermal]) |
| **3996** | click or scan EU-EC-10009656281 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **3997** | click or scan EU-EC-10009655989 | | 2021-08-11 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **3998** | click or scan EU-EC-10009655977 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **3999** | click or scan EU-EC-10009655950 | | 2021-08-11 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **4000** | click or scan EU-EC-10009655809 | | 2021-08-11 | Non Healthcare Professional | Non EEA | Not Specified | Male | Anxiety (n/a - Unknown - ), Behaviour disorder (n/a - Unknown - ), Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Depression (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Mood altered (n/a - Unknown - ), Oral mucosal blistering (n/a - Unknown - ), Suicidal ideation (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |
| **4001** | click or scan EU-EC-10009655688 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Activated partial thromboplastin time prolonged (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Activated partial thromboplastin time shortened (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Acute kidney injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Brain herniation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Brain oedema (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), C-reactive protein increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebral mass effect (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coagulopathy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Coma (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Depressed level of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Epilepsy (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Facial paresis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haemorrhagic transformation stroke (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Haptoglobin increased (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Nervous system disorder (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Oliguria (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4002** | click or scan EU-EC-10009655684 | | 2021-08-11 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) |
| **4003** | click or scan EU-EC-10009655596 | | 2021-08-11 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Atrial fibrillation (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea exertional (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4004** | click or scan EU-EC-10009655146 | | 2021-08-11 | Healthcare Professional | EEA | 18-64 Years | Male | COVID-19 immunisation (n/a - Unknown - ), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4005** | click or scan EU-EC-10009655072 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4006** | click or scan EU-EC-10009654673 | | 2021-08-11 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4007** | click or scan EU-EC-10009654657 | | 2021-08-11 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anti-neutrophil cytoplasmic antibody positive vasculitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pulmonary alveolar haemorrhage (n/a - Unknown - Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition), Slow speech (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4008** | click or scan EU-EC-10009654648 | | 2021-08-11 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4009** | click or scan EU-EC-10009654387 | | 2021-08-11 | Healthcare Professional | EEA | 18-64 Years | Female | Hypopituitarism (n/a - Fatal - **Results in Death**), Paralysis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4010** | click or scan EU-EC-10009654208 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Oral fungal infection (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4011** | click or scan EU-EC-10009654193 | | 2021-08-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (41d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4012** | click or scan EU-EC-10009653722 | | 2021-08-11 | Healthcare Professional | EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4013** | click or scan EU-EC-10009652203 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4014** | click or scan EU-EC-10009651639 | | 2021-08-11 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiorenal syndrome (2wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4015** | click or scan EU-EC-10009651580 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [2s - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4016** | click or scan EU-EC-10009651117 | | 2021-08-11 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **4017** | click or scan EU-EC-10009651098 | | 2021-08-11 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4018** | click or scan EU-EC-10009650892 | | 2021-08-11 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Cerebral artery thrombosis (2d - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Thrombocytopenia (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4019** | click or scan EU-EC-10009648522 | | 2021-08-11 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (12d - Fatal - **Results in Death**), Aortic aneurysm (12d - Fatal - **Results in Death**), Arterial thrombosis (12d - Fatal - **Results in Death**), Gastrointestinal necrosis (12d - Fatal - **Results in Death**), Oedema peripheral (12d - Fatal - **Results in Death**), Rectal haemorrhage (12d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4020** | click or scan EU-EC-10009647587 | | 2021-08-10 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Bacterial infection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Blood loss anaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Haemoglobin decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4021** | click or scan EU-EC-10009646900 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (0d - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral artery occlusion (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4022** | click or scan EU-EC-10009646888 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Female | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4023** | click or scan<br>EU-EC-10009646826 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Adrenal haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Akathisia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral artery occlusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hemiplegia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Intracranial pressure increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Peripheral coldness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Poor peripheral circulation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal haematoma (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Skin discolouration (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Speech disorder (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) |
| **4024** | click or scan<br>EU-EC-10009645689 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiovascular insufficiency (n/a - Unknown - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flank pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1mL - Intramuscular]) |
| **4025** | click or scan<br>EU-EC-10009644745 | | 2021-08-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4026** | click or scan<br>EU-EC-10009644316 | | 2021-08-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4027** | click or scan<br>EU-EC-10009644245 | | 2021-08-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4028** | click or scan<br>EU-EC-10009644244 | | 2021-08-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Hypotension (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4029** | click or scan<br>EU-EC-10009644025 | | 2021-08-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4030** | click or scan EU-EC-10009643547 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Gastrointestinal haemorrhage (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4031** | click or scan EU-EC-10009643475 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Female | Ischaemic stroke (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [VALACICLOVIR] (S - COVID-19 immunisation - Not applicable - [4d - 1{DF} - Oral]) |
| **4032** | click or scan EU-EC-10009643474 | | 2021-08-10 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Parenteral]) |
| **4033** | click or scan EU-EC-10009643472 | | 2021-08-10 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| **4034** | click or scan EU-EC-10009643379 | | 2021-08-10 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4035** | click or scan EU-EC-10009643370 | | 2021-08-10 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4036** | click or scan EU-EC-10009643334 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Prophylaxis - n/a - [1d - .5mL - n/a]), [NEFOPAM, NEFOPAM HYDROCHLORIDE] (S - Abdominal pain - n/a - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (S - Abdominal pain - n/a - [n/a - n/a - n/a]) |
| **4037** | click or scan EU-EC-10009643325 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4038** | click or scan EU-EC-10009643323 | | 2021-08-10 | Healthcare Professional | EEA | 65-85 Years | Male | Condition aggravated (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4039** | click or scan EU-EC-10009643321 | | 2021-08-10 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 pneumonia (n/a - Fatal - **Results in Death**), General physical health deterioration (1wk - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4040** | click or scan EU-EC-10009643002 | | 2021-08-10 | Healthcare Professional | Non EEA | More than 85 Years | Female | Colitis ischaemic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4041** | click or scan EU-EC-10009641852 | | 2021-08-10 | Healthcare Professional | Non EEA | 18-64 Years | Female | Brain compression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain neoplasm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebellar haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebral haemangioma (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial aneurysm (n/a - Unknown - Other Medically Important Condition), Meningioma (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Tumour haemorrhage (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4042** | click or scan EU-EC-10009641563 | | 2021-08-10 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4043** | click or scan EU-EC-10009641462 | | 2021-08-10 | Non Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4044** | click or scan EU-EC-10009641141 | | 2021-08-10 | Healthcare Professional | Non EEA | 18-64 Years | Male | Autopsy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac myxoma (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Congestive cardiomyopathy (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4045** | click or scan EU-EC-10009640966 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Hepatocellular carcinoma (28d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4046** | click or scan EU-EC-10009640921 | | 2021-08-10 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4047** | click or scan EU-EC-10009640617 | | 2021-08-10 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hemiplegia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30s - 1{DF} - Intramuscular]) |
| **4048** | click or scan EU-EC-10009640462 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4049** | click or scan EU-EC-10009639852 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]), PANITUMUMAB [PANITUMUMAB] (S - Colon cancer metastatic - Drug withdrawn - [n/a - n/a - Unknown]) |
| **4050** | click or scan EU-EC-10009639468 | | 2021-08-10 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4051** | click or scan EU-EC-10009638441 | | 2021-08-10 | Healthcare Professional | EEA | More than 85 Years | Male | Death (0d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **4052** | click or scan EU-EC-10009638137 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4053** | click or scan EU-EC-10009637709 | | 2021-08-10 | Healthcare Professional | EEA | 18-64 Years | Male | Loss of consciousness (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| **4054** | click or scan EU-EC-10009637503 | | 2021-08-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hyperventilation (n/a - Unknown - ), Productive cough (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**), Restlessness (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| **4055** | click or scan EU-EC-10009637155 | | 2021-08-10 | Healthcare Professional | Non EEA | 65-85 Years | Female | Somnolence (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4056** | click or scan EU-EC-10009635669 | | 2021-08-10 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (15d - Fatal - **Results in Death**), Interstitial lung disease (15d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4057** | click or scan EU-EC-10009635289 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood creatine phosphokinase increased (n/a - Unknown - ), Blood lactate dehydrogenase increased (n/a - Unknown - ), Fall (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Ovarian cancer (n/a - Fatal - **Results in Death**), Pain (n/a - Unknown - ), Polymyositis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4058** | click or scan EU-EC-10009634860 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4059** | click or scan EU-EC-10009634842 | | 2021-08-09 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (30d - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (30d - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 - Not applicable - [n/a - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4060** | click or scan EU-EC-10009634699 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Anti-platelet antibody (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cerebral artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Portosplenomesenteric venous thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4061** | click or scan EU-EC-10009634544 | | 2021-08-09 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Choking sensation (n/a - Fatal - **Results in Death**), Fatigue (n/a - Recovered/Resolved - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4062** | click or scan EU-EC-10009633787 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4063** | click or scan EU-EC-10009633530 | | 2021-08-09 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Monoplegia (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Vaccination site haematoma (n/a - Not Recovered/Not Resolved - ), Vaccination site nodule (n/a - Not Recovered/Not Resolved - ), Vaccination site scar (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4064** | click or scan EU-EC-10009633474 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4065** | click or scan EU-EC-10009633375 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4066** | click or scan EU-EC-10009633257 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Mucormycosis (n/a - Not Recovered/Not Resolved - ), Septic shock (n/a - Fatal - **Results in Death**), Visual impairment (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4067** | click or scan EU-EC-10009633054 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4068** | click or scan EU-EC-10009632905 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4069** | click or scan EU-EC-10009632237 | | 2021-08-09 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4070** | click or scan EU-EC-10009631839 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4071** | click or scan EU-EC-10009631835 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4072** | click or scan EU-EC-10009631756 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Acute disseminated encephalomyelitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4073** | click or scan EU-EC-10009631722 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [29d - 2{DF} - Intramuscular]) |
| **4074** | click or scan EU-EC-10009631670 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4075** | click or scan EU-EC-10009631637 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [24d - 2{DF} - Intramuscular]) |
| **4076** | click or scan EU-EC-10009631635 | | 2021-08-09 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 2{DF} - Intramuscular]) |
| **4077** | click or scan EU-EC-10009631590 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4078** | click or scan EU-EC-10009631573 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Delirium tremens (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - .5mL - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4079** | click or scan EU-EC-10009631545 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Male | Adrenal mass (0d - Fatal - **Results in Death**), Aortic arteriosclerosis (0d - Fatal - **Results in Death**), Cardiac arrest (0d - Fatal - **Results in Death**), Cardiac ventricular thrombosis (0d - Fatal - **Results in Death**), Diarrhoea (0d - Fatal - **Results in Death**), Gastrointestinal haemorrhage (0d - Fatal - **Results in Death**), Hepatic mass (0d - Fatal - **Results in Death**), Hepatomegaly (0d - Fatal - **Results in Death**), Hypotension (0d - Fatal - **Results in Death**), Pulmonary artery thrombosis (0d - Fatal - **Results in Death**), Pulmonary embolism (0d - Fatal - **Results in Death**), Renal vascular thrombosis (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4080** | click or scan EU-EC-10009631542 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4081** | click or scan EU-EC-10009631388 | | 2021-08-09 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **4082** | click or scan EU-EC-10009631288 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4083** | click or scan EU-EC-10009631283 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **4084** | click or scan EU-EC-10009631261 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4085** | click or scan EU-EC-10009631239 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **4086** | click or scan EU-EC-10009631214 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4087** | click or scan EU-EC-10009630725 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Vaccination site haematoma (n/a - Unknown - ) | COVID-19 VACCINE JANSSEN SUSPENSION FOR INJECTION COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4088** | click or scan EU-EC-10009630462 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Female | Anaemia (83d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling hot (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ), Thrombocytopenia (83d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site haematoma (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaginal haemorrhage (2d - Recovered/Resolved - ), White blood cell disorder (83d - Unknown - ) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4089** | click or scan EU-EC-10009630346 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4090** | click or scan EU-EC-10009629929 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Brain oedema (3d - Fatal - **Results in Death**), Cerebral haemorrhage (3d - Fatal - **Results in Death**), Cerebral mass effect (3d - Fatal - **Results in Death**), Coagulopathy (3d - Fatal - **Results in Death**), Unresponsive to stimuli (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4091** | click or scan EU-EC-10009629835 | | 2021-08-09 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4092** | click or scan EU-EC-10009629831 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4093** | click or scan EU-EC-10009629817 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Bronchospasm (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Diffuse alveolar damage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation), Sensitive skin (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4094** | click or scan EU-EC-10009629814 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Blood pressure increased (n/a - Unknown - ), Mesenteric artery thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4095** | click or scan EU-EC-10009629812 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Hypoxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4096** | click or scan EU-EC-10009629807 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4097** | click or scan EU-EC-10009629802 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Eyelid ptosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Liver disorder (n/a - Recovered/Resolved - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Myasthenia gravis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Rhabdomyolysis (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4098** | click or scan EU-EC-10009629794 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition), Discomfort (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Other Medically Important Condition), Hypopnoea (n/a - Unknown - Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4099** | click or scan EU-EC-10009629648 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Arthralgia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Rash (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4100** | click or scan EU-EC-10009629615 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4101** | click or scan EU-EC-10009629614 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4102** | click or scan EU-EC-10009629613 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4103** | click or scan EU-EC-10009629605 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aortic aneurysm (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4104** | click or scan EU-EC-10009629601 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4105** | click or scan EU-EC-10009629496 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Influenza like illness (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4106** | click or scan EU-EC-10009629477 | | 2021-08-09 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4107** | click or scan EU-EC-10009629337 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Ageusia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4108** | click or scan EU-EC-10009629330 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4109** | click or scan EU-EC-10009629264 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute kidney injury (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyponatraemia (14d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4110** | click or scan EU-EC-10009629152 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4111** | click or scan EU-EC-10009629065 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4112** | click or scan EU-EC-10009628763 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Haemorrhagic cerebral infarction (53d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4113** | click or scan EU-EC-10009628324 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiovascular disorder (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Contusion (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Heparin-induced thrombocytopenia test positive (n/a - Fatal - **Results in Death**), Hypovolaemic shock (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Renal disorder (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4114** | click or scan EU-EC-10009628279 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Injection site haematoma (n/a - Fatal - **Results in Death**), Injection site inflammation (n/a - Fatal - **Results in Death**), Injection site pain (n/a - Fatal - **Results in Death**), Injection site warmth (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4115** | click or scan EU-EC-10009628196 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4116** | click or scan EU-EC-10009627995 | | 2021-08-09 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4117** | click or scan EU-EC-10009627652 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood lactate dehydrogenase increased (n/a - Unknown - ), Haemophagocytic lymphohistiocytosis (n/a - Fatal - **Results in Death**), Liver disorder (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4118** | click or scan EU-EC-10009627644 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4119** | click or scan EU-EC-10009627631 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Hypokalaemia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4120** | click or scan EU-EC-10009627611 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure immeasurable (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (n/a - Fatal - **Results in Death**), Moaning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4121** | click or scan EU-EC-10009627594 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Male | Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4122** | click or scan EU-EC-10009626736 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4123** | click or scan EU-EC-10009626714 | | 2021-08-09 | Healthcare Professional | EEA | 18-64 Years | Female | Blood albumin decreased (n/a - Fatal - **Results in Death**), Capillary leak syndrome (n/a - Fatal - **Results in Death**), Capillary nail refill test abnormal (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Ejection fraction decreased (n/a - Fatal - **Results in Death**), Haematocrit increased (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Hypovolaemia (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Myocardial depression (n/a - Fatal - **Results in Death**), Presyncope (n/a - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**), Vasoplegia syndrome (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4124** | click or scan EU-EC-10009626373 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pericardial effusion (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4125** | click or scan EU-EC-10009626364 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Cardiac tamponade (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4126** | click or scan EU-EC-10009626352 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Duodenal ulcer haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Shock haemorrhagic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4127** | click or scan EU-EC-10009625844 | | 2021-08-09 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiomyopathy (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Headache (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **4128** | click or scan EU-EC-10009625666 | | 2021-08-09 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4129** | click or scan EU-EC-10009625624 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Bradykinesia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Dysstasia (n/a - Unknown - ), Fall (n/a - Unknown - Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**), Near drowning (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - **Results in Death**), Skin laceration (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4130** | click or scan EU-EC-10009625304 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4131** | click or scan EU-EC-10009625285 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4132** | click or scan EU-EC-10009625275 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4133** | click or scan EU-EC-10009625257 | | 2021-08-09 | Healthcare Professional | Non EEA | 18-64 Years | Female | Bronchospasm (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4134** | click or scan EU-EC-10009625254 | | 2021-08-09 | Healthcare Professional | Non EEA | More than 85 Years | Female | Completed suicide (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4135** | click or scan EU-EC-10009625253 | | 2021-08-09 | Non Healthcare Professional | EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4136** | click or scan EU-EC-10009625089 | | 2021-08-09 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Foaming at mouth (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4137** | click or scan EU-EC-10009624192 | | 2021-08-08 | Healthcare Professional | EEA | 65-85 Years | Female | Affect lability (95d - Fatal - **Results in Death**), Asthenia (95d - Fatal - **Results in Death**), Dysarthria (95d - Fatal - **Results in Death**), Gait disturbance (95d - Fatal - **Results in Death**), Rash (95d - Fatal - **Results in Death**), Rash pruritic (95d - Fatal - **Results in Death**), Visual impairment (95d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **4138** | click or scan EU-EC-10009623994 | | 2021-08-07 | Non Healthcare Professional | EEA | Not Specified | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **4139** | click or scan EU-EC-10009623981 | | 2021-08-07 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **4140** | click or scan EU-EC-10009623854 | | 2021-08-07 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4141** | click or scan EU-EC-10009623617 | | 2021-08-07 | Healthcare Professional | EEA | 65-85 Years | Female | Agitation (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Choking (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Headache (n/a - Unknown - ), Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - ), Paralysis (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - 1mL - Intramuscular]) |
| **4142** | click or scan EU-EC-10009623269 | | 2021-08-07 | Non Healthcare Professional | Non EEA | Not Specified | Male | Haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Hypertension (n/a - Unknown - **Results in Death**), Hypokinesia (n/a - Unknown - **Results in Death**), Paraesthesia (n/a - Unknown - **Results in Death**), Peripheral swelling (n/a - Unknown - **Results in Death**), Vision blurred (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4143** | click or scan EU-EC-10009623266 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Congestive cardiomyopathy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Heart valve incompetence (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Joint swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4144** | click or scan EU-EC-10009623194 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal discomfort (n/a - Not Recovered/Not Resolved - **Results in Death**), Hepatic failure (n/a - Not Recovered/Not Resolved - **Results in Death**), Ischaemic stroke (n/a - Recovered/Resolved - **Results in Death**), Pancreatitis (17d - Fatal - **Results in Death**), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4145** | click or scan EU-EC-10009623179 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arteriosclerosis coronary artery (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4146** | click or scan EU-EC-10009623172 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - n/a]) |
| **4147** | click or scan EU-EC-10009622989 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Completed suicide (n/a - Fatal - **Results in Death**), Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Delusion (n/a - Not Recovered/Not Resolved - **Results in Death**), Mood altered (n/a - Not Recovered/Not Resolved - **Results in Death**), Suicidal ideation (n/a - Not Recovered/Not Resolved - **Results in Death**), Thinking abnormal (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4148** | click or scan EU-EC-10009622974 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Confusional state (n/a - Not Recovered/Not Resolved - **Results in Death**), Confusional state (n/a - Unknown - **Results in Death**), Crepitations (n/a - Unknown - **Results in Death**), Cystitis (n/a - Not Recovered/Not Resolved - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Fluid retention (n/a - Unknown - **Results in Death**), Respiration abnormal (n/a - Unknown - **Results in Death**), Syncope (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4149** | click or scan EU-EC-10009622970 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Death (5d - Fatal - **Results in Death**, Life Threatening), Illness (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4150** | click or scan EU-EC-10009622895 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Malaise (n/a - Unknown - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - n/a]) |
| **4151** | click or scan EU-EC-10009622770 | | 2021-08-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination site rash (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4152** | click or scan EU-EC-10009622765 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (12d - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [1d - n/a - n/a]) |
| **4153** | click or scan EU-EC-10009622671 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - n/a]) |
| **4154** | click or scan EU-EC-10009622664 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (5d - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - Parenteral]) |
| **4155** | click or scan EU-EC-10009622644 | | 2021-08-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Disabling), Paralysis (46d - Fatal - **Results in Death**, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4156** | click or scan EU-EC-10009622614 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - n/a]) |
| **4157** | click or scan EU-EC-10009622610 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Female | Headache (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic vein thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Hypoperfusion (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Jugular vein thrombosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Photophobia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Portal vein thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4158** | click or scan EU-EC-10009622485 | | 2021-08-07 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Death (1d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - n/a]) |
| **4159** | click or scan EU-EC-10009622329 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [1d - n/a - n/a]) |
| **4160** | click or scan EU-EC-10009622222 | | 2021-08-07 | Healthcare Professional | Non EEA | 18-64 Years | Male | Seizure (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - n/a]) |
| **4161** | click or scan EU-EC-10009622192 | | 2021-08-07 | Healthcare Professional | Non EEA | Not Specified | Female | Carotid artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral artery thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhagic transformation stroke (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [1d - n/a - n/a]) |
| **4162** | click or scan EU-EC-10009622180 | | 2021-08-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4163** | click or scan EU-EC-10009622174 | | 2021-08-07 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4164** | click or scan EU-EC-10009622121 | | 2021-08-07 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Erectile dysfunction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - n/a]) |
| **4165** | click or scan EU-EC-10009621645 | | 2021-08-07 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4166** | click or scan EU-EC-10009620940 | | 2021-08-07 | Healthcare Professional | Non EEA | 65-85 Years | Female | Chest discomfort (n/a - Unknown - ), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4167** | click or scan EU-EC-10009620878 | | 2021-08-07 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myalgia (n/a - Fatal - **Results in Death**), Pulmonary fibrosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **4168** | click or scan EU-EC-10009620740 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4169** | click or scan EU-EC-10009620717 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4170** | click or scan EU-EC-10009620697 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4171** | click or scan EU-EC-10009620686 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4172** | click or scan EU-EC-10009620667 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Loss of consciousness (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4173** | click or scan EU-EC-10009620659 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Unknown - ), Bradyphrenia (n/a - Unknown - ), Fatigue (1d - Fatal - **Results in Death**), Lethargy (1d - Fatal - **Results in Death**), Malaise (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4174** | click or scan EU-EC-10009620636 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (90min - Fatal - **Results in Death**, Other Medically Important Condition), Cold sweat (90min - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (90min - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4175** | click or scan EU-EC-10009620616 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Diarrhoea (1d - Fatal - **Results in Death**), Fatigue (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4176** | click or scan EU-EC-10009620604 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4177** | click or scan EU-EC-10009620593 | | 2021-08-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Coma (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4178** | click or scan EU-EC-10009620578 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4179** | click or scan EU-EC-10009620577 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest discomfort (57h - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (9h - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4180** | click or scan EU-EC-10009620540 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (10d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Pyrexia (10d - Fatal - **Results in Death**), Vaccination complication (10d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4181** | click or scan EU-EC-10009620288 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4182** | click or scan EU-EC-10009620102 | | 2021-08-06 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Abortion spontaneous (n/a - Fatal - **Results in Death**, Life Threatening, Congenital Anomaly, Other Medically Important Condition), Congenital anomaly (n/a - Fatal - **Results in Death**, Life Threatening, Congenital Anomaly, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **4183** | click or scan EU-EC-10009620016 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4184** | click or scan EU-EC-10009619771 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (6d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4185** | click or scan EU-EC-10009619050 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4186** | click or scan EU-EC-10009618838 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Unknown - Other Medically Important Condition), Haematuria (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4187** | click or scan EU-EC-10009618810 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Depressed level of consciousness (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Lethargy (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4188** | click or scan EU-EC-10009618752 | | 2021-08-06 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Herpes zoster meningitis (n/a - Unknown - Other Medically Important Condition), Meningitis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4189** | click or scan EU-EC-10009618505 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cellulitis (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Pollakiuria (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4190** | click or scan EU-EC-10009618004 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Drug-induced liver injury (n/a - Fatal - **Results in Death**), Encephalitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]), IPILIMUMAB [IPILIMUMAB] (S - Malignant melanoma - n/a - [n/a - n/a - Intravenous (not otherwise specified)]), NIVOLUMAB [NIVOLUMAB] (S - Malignant melanoma - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) |
| **4191** | click or scan EU-EC-10009617819 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atelectasis (n/a - Unknown - ), Autoimmune haemolytic anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**), Diverticulum intestinal (n/a - Unknown - ), Haemolysis (n/a - Fatal - **Results in Death**), Jaundice (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal cyst (n/a - Unknown - ), Spinal disorder (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4192** | click or scan EU-EC-10009617713 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4193** | click or scan EU-EC-10009617712 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4194** | click or scan EU-EC-10009617440 | | 2021-08-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4195** | click or scan EU-EC-10009617303 | | 2021-08-06 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4196** | click or scan EU-EC-10009617199 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4197** | click or scan EU-EC-10009617115 | | 2021-08-06 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4198** | click or scan EU-EC-10009617007 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Insomnia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4199** | click or scan EU-EC-10009616963 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1 {DF} - n/a]) |
| **4200** | click or scan EU-EC-10009616747 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4201** | click or scan EU-EC-10009616688 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Antinuclear antibody positive (n/a - Unknown - ), Blood folate decreased (n/a - Unknown - ), Blood pressure decreased (n/a - Unknown - ), Blood pressure systolic decreased (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebral atrophy (n/a - Unknown - Other Medically Important Condition), Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Feeding disorder (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), Immune thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Inflammation (n/a - Unknown - ), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Shunt stenosis (n/a - Unknown - ), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thyroid function test abnormal (n/a - Unknown - ), Vitamin B12 abnormal (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4202** | click or scan EU-EC-10009616443 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4203** | click or scan EU-EC-10009616392 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - ), Cold sweat (n/a - Unknown - ), Dyspnoea (n/a - Fatal - **Results in Death**), Emotional distress (n/a - Unknown - ), Feeling cold (n/a - Unknown - ), Feeling hot (n/a - Unknown - ), Feeling of body temperature change (n/a - Unknown - ), Micturition urgency (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4204** | click or scan EU-EC-10009616073 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Presyncope (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **4205** | click or scan EU-EC-10009615999 | | 2021-08-06 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4206** | click or scan EU-EC-10009615996 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4207** | click or scan EU-EC-10009615995 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **4208** | click or scan EU-EC-10009615979 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Female | Pancreatitis acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4209** | click or scan EU-EC-10009615976 | | 2021-08-06 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4210** | click or scan EU-EC-10009615919 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **4211** | click or scan EU-EC-10009615713 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4212** | click or scan EU-EC-10009615683 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4213** | click or scan EU-EC-10009615403 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4214** | click or scan EU-EC-10009615398 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Choking (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Feeding disorder (n/a - Unknown - ), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4215** | click or scan EU-EC-10009615212 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in jaw (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4216** | click or scan EU-EC-10009615174 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Respiration abnormal (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4217** | click or scan EU-EC-10009614951 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Atrioventricular block complete (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4218** | click or scan EU-EC-10009614942 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Anxiety (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Eye pruritus (n/a - Unknown - ), Fracture (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ), Paraesthesia oral (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4219** | click or scan EU-EC-10009614940 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aphasia (n/a - Unknown - ), Cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemiplegia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4220** | click or scan EU-EC-10009614919 | | 2021-08-06 | Non Healthcare Professional | Non EEA | Not Specified | Male | Illness (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4221** | click or scan EU-EC-10009614813 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4222** | click or scan EU-EC-10009614649 | | 2021-08-06 | Non Healthcare Professional | EEA | Not Specified | Male | Cardiac disorder (n/a - Unknown - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Medication error (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]), NOT AVAILABLE [BNT 162] (S - Immunisation - n/a - [n/a - n/a - Unknown]), NOT AVAILABLE [MRNA 1273] (S - Immunisation - n/a - [n/a - n/a - Unknown]) |
| **4223** | click or scan EU-EC-10009614414 | | 2021-08-06 | Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (n/a - Fatal - **Results in Death**), SARS-CoV-2 test negative (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) |
| **4224** | click or scan EU-EC-10009613859 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4225** | click or scan EU-EC-10009613461 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neck mass (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4226** | click or scan EU-EC-10009612439 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4227** | click or scan EU-EC-10009612402 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4228** | click or scan EU-EC-10009612121 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ascites (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coagulopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dementia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oedema peripheral (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritonitis bacterial (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4229** | click or scan EU-EC-10009612085 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Retching (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4230** | click or scan EU-EC-10009611866 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Aggression (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Hyperammonaemia (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Unknown - ), Metabolic encephalopathy (n/a - Fatal - **Results in Death**), Pancytopenia (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - ) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - n/a - Dose increased - [n/a - n/a - n/a]), [TACROLIMUS] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]) |
| **4231** | click or scan EU-EC-10009611794 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Feeding disorder (n/a - Unknown - ), Pyrexia (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4232** | click or scan EU-EC-10009611496 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Not Specified | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4233** | click or scan EU-EC-10009611438 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood culture negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood test (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest X-ray (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Computerised tomogram abdomen (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Culture urine negative (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mental status changes (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Ovarian vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urine analysis normal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4234** | click or scan EU-EC-10009611437 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4235** | click or scan EU-EC-10009611379 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Male | Vascular stent thrombosis (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4236** | click or scan EU-EC-10009611130 | | 2021-08-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Encephalitis viral (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4237** | click or scan EU-EC-10009611128 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Haematemesis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4238** | click or scan EU-EC-10009611016 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Female | C-reactive protein increased (14d - Fatal - **Results in Death**), Death (14d - Fatal - **Results in Death**), General physical health deterioration (14d - Fatal - **Results in Death**), Inflammation (14d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4239** | click or scan EU-EC-10009610937 | | 2021-08-06 | Healthcare Professional | EEA | 18-64 Years | Female | Acute kidney injury (n/a - Fatal - **Results in Death**), Cardiogenic shock (n/a - Fatal - **Results in Death**), Cardiomyopathy (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4240** | click or scan EU-EC-10009610868 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Amylase increased (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Blood lactate dehydrogenase increased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest X-ray abnormal (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4241** | click or scan EU-EC-10009610720 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Fatigue (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4242** | click or scan EU-EC-10009610715 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4243** | click or scan EU-EC-10009610616 | | 2021-08-06 | Healthcare Professional | EEA | More than 85 Years | Male | Acute myocardial infarction (1d - Fatal - **Results in Death**), Angina pectoris (1d - Fatal - **Results in Death**), Cardiovascular disorder (1d - Fatal - **Results in Death**), Coronary artery occlusion (1d - Fatal - **Results in Death**), Ejection fraction decreased (1d - Fatal - **Results in Death**), Fall (1d - Fatal - **Results in Death**), Fibrin D dimer increased (1d - Fatal - **Results in Death**), Hypotension (1d - Fatal - **Results in Death**), Muscular weakness (1d - Fatal - **Results in Death**), Shock (1d - Fatal - **Results in Death**), Troponin increased (1d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4244** | click or scan EU-EC-10009610499 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4245** | click or scan EU-EC-10009610313 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4246** | click or scan EU-EC-10009610288 | | 2021-08-06 | Non Healthcare Professional | EEA | 18-64 Years | Female | Abdominal pain upper (n/a - Unknown - ), Aortic thrombosis (n/a - Unknown - Life Threatening), Diarrhoea (n/a - Unknown - ), Haemorrhage (n/a - Unknown - Life Threatening), Infarction (n/a - Unknown - Life Threatening), Pain (n/a - Unknown - Life Threatening), Portal vein thrombosis (n/a - Unknown - Life Threatening), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4247** | click or scan EU-EC-10009610221 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cough (n/a - Fatal - **Results in Death**), Interstitial lung disease (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection viral (n/a - Unknown - Other Medically Important Condition), Pneumonia bacterial (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**), Right ventricular systolic pressure increased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4248** | click or scan EU-EC-10009610215 | | 2021-08-06 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Bleeding time prolonged (n/a - Fatal - **Results in Death**), Chest pain (n/a - Fatal - **Results in Death**), Confusional state (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4249** | click or scan EU-EC-10009609963 | | 2021-08-06 | Healthcare Professional | EEA | More than 85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4250** | click or scan EU-EC-10009609805 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4251** | click or scan EU-EC-10009609600 | | 2021-08-06 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthma (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Diverticulitis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Emphysema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypertension (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4252** | click or scan EU-EC-10009609311 | | 2021-08-06 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4253** | click or scan EU-EC-10009609283 | | 2021-08-06 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Local reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4254** | click or scan EU-EC-10009609067 | | 2021-08-06 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decreased appetite (n/a - Unknown - ), Diabetes mellitus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetic coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4255** | click or scan EU-EC-10009608615 | | 2021-08-06 | Healthcare Professional | EEA | 65-85 Years | Male | Dyspnoea exertional (15d - Fatal - **Results in Death**), Gastrointestinal haemorrhage (15d - Fatal - **Results in Death**), Renal failure (15d - Fatal - **Results in Death**), Sepsis (15d - Fatal - **Results in Death**), Skin ulcer (15d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4256** | click or scan EU-EC-10009606215 | | 2021-08-06 | Non Healthcare Professional | EEA | 65-85 Years | Male | Chest discomfort (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) |
| **4257** | click or scan EU-EC-10009607518 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4258** | click or scan EU-EC-10009607488 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4259** | click or scan EU-EC-10009607474 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pain in extremity (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4260** | click or scan EU-EC-10009607458 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Concomitant disease progression (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4261** | click or scan EU-EC-10009607044 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arrhythmia (n/a - Recovered/Resolved - Other Medically Important Condition), Electrocardiogram T wave inversion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved - ), Infection susceptibility increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Left ventricular hypertrophy (n/a - Not Recovered/Not Resolved - ), Pneumocystis jirovecii pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary congestion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]), [PREDNISOLONE] (S - Prostate cancer - Not applicable - [n/a - 10mg - Oral]) |
| **4262** | click or scan EU-EC-10009607011 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Contusion (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Red blood cell count decreased (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4263** | click or scan EU-EC-10009606691 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Pneumonia (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) |
| **4264** | click or scan EU-EC-10009606500 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4265** | click or scan EU-EC-10009606486 | | 2021-08-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (2d - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4266** | click or scan EU-EC-10009605809 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4267** | click or scan EU-EC-10009605513 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4268** | click or scan EU-EC-10009605148 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Encephalopathy (n/a - Fatal - **Results in Death**), Gastrointestinal disorder (n/a - Fatal - **Results in Death**), Haemodynamic instability (n/a - Fatal - **Results in Death**), Liver injury (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Supraventricular tachycardia (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4269** | click or scan EU-EC-10009604972 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute respiratory distress syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**), Eosinophilic bronchitis (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4270** | click or scan EU-EC-10009604935 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4271** | click or scan EU-EC-10009604934 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4272** | click or scan EU-EC-10009604933 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Anaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematochezia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Internal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Large intestinal haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Melaena (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myelodysplastic syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4273** | click or scan EU-EC-10009604660 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4274** | click or scan EU-EC-10009604632 | | 2021-08-05 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Febrile convulsion (n/a - Fatal - **Results in Death**), Local reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4275** | click or scan EU-EC-10009604618 | | 2021-08-05 | Non Healthcare Professional | Non EEA | Not Specified | Female | Hydrops foetalis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **4276** | click or scan EU-EC-10009604588 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic valve incompetence (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4277** | click or scan EU-EC-10009604265 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4278** | click or scan EU-EC-10009604250 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Anxiety (n/a - Unknown - ), Completed suicide (n/a - Fatal - **Results in Death**), Disease recurrence (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Mental disorder (n/a - Unknown - ), Neurosis (n/a - Unknown - ), Paranoia (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4279** | click or scan EU-EC-10009603294 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Brain death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4280** | click or scan EU-EC-10009603268 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4281** | click or scan EU-EC-10009602942 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4282** | click or scan EU-EC-10009602568 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4283** | click or scan EU-EC-10009602497 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4284** | click or scan EU-EC-10009602351 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4285** | click or scan EU-EC-10009602278 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4286** | click or scan EU-EC-10009602188 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [19d - 2{DF} - Intramuscular]) |
| **4287** | click or scan EU-EC-10009602093 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Confusional state (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - n/a - [n/a - n/a - n/a]) |
| **4288** | click or scan EU-EC-10009601944 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulse pressure decreased (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4289** | click or scan EU-EC-10009601934 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4290** | click or scan EU-EC-10009601767 | | 2021-08-05 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **4291** | click or scan EU-EC-10009601602 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Fatal - **Results in Death**), Respiratory arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4292** | click or scan EU-EC-10009601258 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (8d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S- COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4293** | click or scan EU-EC-10009601236 | | 2021-08-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Fall (0d - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening), Seizure (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S- COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4294** | click or scan EU-EC-10009601182 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ), Foaming at mouth (n/a - Unknown - ), SARS-CoV-2 antibody test positive (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4295** | click or scan EU-EC-10009601179 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiomegaly (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - **Results in Death**), Disorientation (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**), Hypoventilation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nodule (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Rales (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - **Results in Death**), Somnolence (n/a - Fatal - **Results in Death**), Suspected COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Wheezing (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4296** | click or scan EU-EC-10009601166 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Unknown - ), Nausea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4297** | click or scan EU-EC-10009601150 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - ), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4298** | click or scan EU-EC-10009601146 | | 2021-08-05 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate abnormal (n/a - Fatal - **Results in Death**, Life Threatening), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **4299** | click or scan EU-EC-10009601125 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4300** | click or scan EU-EC-10009601112 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Local reaction (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4301** | click or scan EU-EC-10009600918 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Throat tightness (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4302** | click or scan EU-EC-10009600867 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4303** | click or scan EU-EC-10009600802 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Muscle spasms (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4304** | click or scan EU-EC-10009600508 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Discomfort (1d - Fatal - **Results in Death**), Dyspnoea (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4305** | click or scan EU-EC-10009600438 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4306** | click or scan EU-EC-10009599755 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arteriosclerosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Arteriosclerosis coronary artery (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coronary artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), ECG signs of myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | SPIKEVAX COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) DISPERSION FOR INJECTION [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - .5mL - Intramuscular]) |
| **4307** | click or scan EU-EC-10009599736 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4308** | click or scan EU-EC-10009599629 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Aneurysm (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4309** | click or scan EU-EC-10009599622 | | 2021-08-05 | Non Healthcare Professional | EEA | 18-64 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4310** | click or scan EU-EC-10009599616 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Male | Cough (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4311** | click or scan EU-EC-10009599577 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4312** | click or scan EU-EC-10009599565 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4313** | click or scan EU-EC-10009599556 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4314** | click or scan EU-EC-10009599497 | | 2021-08-05 | Healthcare Professional | EEA | Not Specified | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4315** | click or scan EU-EC-10009599251 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4316** | click or scan EU-EC-10009599101 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4317** | click or scan EU-EC-10009598994 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Local reaction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4318** | click or scan EU-EC-10009598988 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Diarrhoea (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4319** | click or scan EU-EC-10009598983 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Anuria (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Headache (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4320** | click or scan EU-EC-10009598885 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (13d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4321** | click or scan EU-EC-10009598839 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | Coagulopathy (5d - Fatal - **Results in Death**), Death (5d - Fatal - **Results in Death**), Haemorrhagic transformation stroke (5d - Fatal - **Results in Death**), Hemiplegia (5d - Fatal - **Results in Death**), Ischaemic stroke (5d - Fatal - **Results in Death**), Nerve compression (5d - Fatal - **Results in Death**), Nervous system disorder (5d - Fatal - **Results in Death**), Thrombocytopenia (5d - Fatal - **Results in Death**), Thrombosis (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4322** | click or scan EU-EC-10009598815 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4323** | click or scan EU-EC-10009598748 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Back pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4324** | click or scan EU-EC-10009598690 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4325** | click or scan EU-EC-10009598653 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (2d - Fatal - **Results in Death**), Altered state of consciousness (1d - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Hemiplegia (1d - Fatal - **Results in Death**), Hypoxia (1d - Fatal - **Results in Death**), International normalised ratio increased (2d - Fatal - **Results in Death**), Ischaemic stroke (1d - Fatal - **Results in Death**), Pulmonary embolism (1d - Fatal - **Results in Death**), Thrombocytopenia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4326** | click or scan EU-EC-10009598647 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4327** | click or scan EU-EC-10009598620 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | Atrioventricular block complete (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4328** | click or scan EU-EC-10009598590 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (6d - Fatal - **Results in Death**, Other Medically Important Condition), Hypoxia (6d - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4329** | click or scan EU-EC-10009598505 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Coronary artery occlusion (n/a - Unknown - Other Medically Important Condition), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - **Results in Death**), Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4330** | click or scan EU-EC-10009598500 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dry mouth (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4331** | click or scan EU-EC-10009598492 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Neck pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4332** | click or scan EU-EC-10009598244 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | Heart rate increased (13d - Fatal - **Results in Death**), Hemiparesis (13d - Fatal - **Results in Death**), Hypertension (13d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4333** | click or scan EU-EC-10009598216 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Male | Erythema (n/a - Unknown - ), Exposure to SARS-CoV-2 (0d - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Sudden unexplained death in epilepsy (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4334** | click or scan EU-EC-10009598176 | | 2021-08-05 | Non Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4335** | click or scan EU-EC-10009598168 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4336** | click or scan EU-EC-10009598164 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dyspnoea exertional (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4337** | click or scan EU-EC-10009598155 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Renal failure (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4338** | click or scan EU-EC-10009598041 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | Back pain (n/a - Fatal - **Results in Death**), Blood alkaline phosphatase increased (n/a - Fatal - **Results in Death**), Burning sensation (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Coagulopathy (n/a - Fatal - **Results in Death**), Cutaneous vasculitis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fibrin D dimer increased (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Skin disorder (n/a - Fatal - **Results in Death**), Spinal pain (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**), Urticaria (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4339** | click or scan EU-EC-10009597752 | | 2021-08-05 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4340** | click or scan EU-EC-10009597751 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Decreased appetite (n/a - Not Recovered/Not Resolved - ), Hypersensitivity (n/a - Unknown - ), Nausea (165min - Recovered/Resolved - ), Pneumonia (n/a - Recovering/Resolving - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4341** | click or scan EU-EC-10009597748 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Bronchospasm (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4342** | click or scan EU-EC-10009597480 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4343** | click or scan EU-EC-10009597243 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), LIXIANA [EDOXABAN, EDOXABAN TOSYLATE] (S - Atrial fibrillation - Unknown - [n/a - 30mg - Oral]) |
| **4344** | click or scan EU-EC-10009597240 | | 2021-08-05 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4345** | click or scan EU-EC-10009597225 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4346** | click or scan EU-EC-10009597210 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Respiration abnormal (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4347** | click or scan EU-EC-10009597139 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4348** | click or scan EU-EC-10009597137 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4349** | click or scan EU-EC-10009597136 | | 2021-08-05 | Healthcare Professional | EEA | 18-64 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4350** | click or scan EU-EC-10009597135 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4351** | click or scan EU-EC-10009597133 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4352** | click or scan EU-EC-10009597132 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4353** | click or scan EU-EC-10009597130 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4354** | click or scan EU-EC-10009597129 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4355** | click or scan EU-EC-10009597128 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4356** | click or scan EU-EC-10009597127 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4357** | click or scan EU-EC-10009597126 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4358** | click or scan EU-EC-10009597125 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4359** | click or scan EU-EC-10009597124 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4360** | click or scan EU-EC-10009597051 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4361** | click or scan EU-EC-10009597050 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4362** | click or scan EU-EC-10009597049 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4363** | click or scan EU-EC-10009597048 | | 2021-08-05 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4364** | click or scan EU-EC-10009596959 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4365** | click or scan EU-EC-10009596854 | | 2021-08-05 | Healthcare Professional | Non EEA | Not Specified | Male | Tremor (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4366** | click or scan EU-EC-10009596809 | | 2021-08-05 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4367** | click or scan EU-EC-10009596797 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Female | Gastrointestinal necrosis (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4368** | click or scan EU-EC-10009596796 | | 2021-08-05 | Healthcare Professional | Non EEA | More than 85 Years | Male | Nausea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4369** | click or scan EU-EC-10009596759 | | 2021-08-05 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4370** | click or scan EU-EC-10009595962 | | 2021-08-05 | Healthcare Professional | EEA | More than 85 Years | Male | Cardiac arrest (0d - Fatal - **Results in Death**), Death (0d - Fatal - **Results in Death**), Malaise (0d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4371** | click or scan EU-EC-10009595960 | | 2021-08-05 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4372** | click or scan EU-EC-10009594708 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aortic aneurysm rupture (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4373** | click or scan EU-EC-10009593646 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4374** | click or scan EU-EC-10009593524 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4375** | click or scan EU-EC-10009593428 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (1d - Fatal - **Results in Death**, Other Medically Important Condition), Cyanosis (1d - Unknown - ), Dizziness (1d - Unknown - ), Skin warm (1d - Unknown - ), Vaccination complication (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4376** | click or scan EU-EC-10009593023 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pyrexia (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4377** | click or scan EU-EC-10009592896 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4378** | click or scan EU-EC-10009592825 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (9d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4379** | click or scan EU-EC-10009592773 | | 2021-08-04 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4380** | click or scan EU-EC-10009592712 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Dysarthria (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4381** | click or scan EU-EC-10009592578 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4382** | click or scan EU-EC-10009592425 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**), Constipation (n/a - Unknown - ), Cystitis (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4383** | click or scan EU-EC-10009592152 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ageusia (n/a - Not Recovered/Not Resolved - ), Anosmia (n/a - Not Recovered/Not Resolved - ), COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - ), Pharyngeal swelling (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4384** | click or scan EU-EC-10009592018 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (1d - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a - More in ICSR]) |
| **4385** | click or scan EU-EC-10009590991 | | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cerebral venous thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4386** | click or scan EU-EC-10009590950 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4387** | click or scan EU-EC-10009590934 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4388** | click or scan EU-EC-10009590924 | | 2021-08-04 | Non Healthcare Professional | EEA | Not Specified | Male | Cerebrovascular accident (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4389** | click or scan EU-EC-10009590479 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asphyxia (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Cough (n/a - Unknown - ), Cyanosis central (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Fall (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Tachycardia (n/a - Unknown - ), Tachypnoea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4390** | click or scan EU-EC-10009590239 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 2 {DF} - Intramuscular]) |
| **4391** | click or scan EU-EC-10009590196 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4392** | click or scan EU-EC-10009590147 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Pyrexia (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1 {DF} - Intramuscular]) |
| **4393** | click or scan EU-EC-10009590055 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1 {DF} - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4394** | click or scan EU-EC-10009590053 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Female | Vaccination failure (35d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [20d - 2{DF} - Intramuscular]) |
| **4395** | click or scan EU-EC-10009589661 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Chest pain (4d - Recovered/Resolved - ), Coronary artery disease (0d - Fatal - **Results in Death**), Dyspnoea (4d - Recovered/Resolved - ), Headache (4d - Recovered/Resolved - ), Myalgia (4d - Recovered/Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4396** | click or scan EU-EC-10009589409 | | 2021-08-04 | Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4397** | click or scan EU-EC-10009589384 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bundle branch block right (n/a - Unknown - Other Medically Important Condition), Cerebral infarction (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - **Results in Death**), Cold sweat (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4398** | click or scan EU-EC-10009589376 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4399** | click or scan EU-EC-10009589350 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Condition aggravated (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Unknown - ), Pulmonary fibrosis (n/a - Fatal - **Results in Death**), Tachypnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4400** | click or scan EU-EC-10009588922 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4401** | click or scan EU-EC-10009588723 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Arthralgia (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Back pain (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Local reaction (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Tenderness (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4402** | click or scan EU-EC-10009588573 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4403** | click or scan EU-EC-10009588524 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4404** | click or scan EU-EC-10009588518 | | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4405** | click or scan EU-EC-10009588510 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Abscess neck (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Head discomfort (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4406** | click or scan EU-EC-10009588500 | | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Meningoencephalitis herpetic (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4407** | click or scan EU-EC-10009588342 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | Blood urine present (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Eschar (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4408** | click or scan EU-EC-10009588239 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | Cardiac failure (14d - Fatal - **Results in Death**, Life Threatening), Cardiovascular disorder (14d - Fatal - **Results in Death**, Life Threatening), Dyspnoea (14d - Fatal - **Results in Death**, Life Threatening), N-terminal prohormone brain natriuretic peptide increased (14d - Fatal - **Results in Death**, Life Threatening), Respiratory disorder (14d - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4409** | click or scan EU-EC-10009588097 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Cerebrovascular accident (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Right ventricular failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4410** | click or scan EU-EC-10009588095 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Laboratory test (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4411** | click or scan EU-EC-10009588043 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Aspiration (n/a - Fatal - **Results in Death**), Asthenia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **4412** | click or scan EU-EC-10009587909 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Facial paralysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Haemorrhagic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hemiplegia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Movement disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Slow response to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4413** | click or scan EU-EC-10009587790 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4414** | click or scan EU-EC-10009587574 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4415** | click or scan EU-EC-10009587573 | | 2021-08-04 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4416** | click or scan EU-EC-10009587571 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Female | Autopsy (n/a - Fatal - **Results in Death**), Cardiac arrest (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4417** | click or scan EU-EC-10009587412 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4418** | click or scan EU-EC-10009587205 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Haemoptysis (0d - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pneumonia bacterial (n/a - Fatal - **Results in Death**), Pulmonary alveolar haemorrhage (n/a - Fatal - **Results in Death**), Pulmonary oedema (n/a - Fatal - **Results in Death**), SARS-CoV-2 test positive (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4419** | click or scan EU-EC-10009587126 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |
| **4420** | click or scan EU-EC-10009587052 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4421** | click or scan EU-EC-10009587048 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (11d - Fatal - **Results in Death**), Cerebral ischaemia (11d - Fatal - **Results in Death**), Hemiplegia (11d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4422** | click or scan EU-EC-10009587036 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4423** | click or scan EU-EC-10009587021 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4424** | click or scan EU-EC-10009586986 | | 2021-08-04 | Non Healthcare Professional | EEA | More than 85 Years | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4425** | click or scan EU-EC-10009586970 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4426** | click or scan EU-EC-10009586968 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4427** | click or scan EU-EC-10009586866 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | Death (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4428** | click or scan EU-EC-10009586822 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4429** | click or scan EU-EC-10009586498 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4430** | click or scan EU-EC-10009586443 | | 2021-08-04 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**), Vaginal haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4431** | click or scan EU-EC-10009586001 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dysarthria (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4432** | click or scan EU-EC-10009585682 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4433** | click or scan EU-EC-10009585528 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Drowning (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **4434** | click or scan EU-EC-10009585382 | | 2021-08-04 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac disorder (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4435** | click or scan EU-EC-10009585019 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Ischaemia (n/a - Fatal - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4436** | click or scan EU-EC-10009584761 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4437** | click or scan EU-EC-10009584338 | | 2021-08-04 | Non Healthcare Professional | EEA | 18-64 Years | Female | Incorrect route of product administration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**), Medication error (n/a - Fatal - **Results in Death**) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral]) |
| **4438** | click or scan EU-EC-10009584335 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4439** | click or scan EU-EC-10009584334 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4440** | click or scan EU-EC-10009584333 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4441** | click or scan EU-EC-10009584332 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4442** | click or scan EU-EC-10009584331 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4443** | click or scan EU-EC-10009584330 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4444** | click or scan EU-EC-10009584329 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4445** | click or scan EU-EC-10009584328 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4446** | click or scan EU-EC-10009584327 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4447** | click or scan EU-EC-10009584326 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4448** | click or scan EU-EC-10009584248 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4449** | click or scan EU-EC-10009584247 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4450** | click or scan EU-EC-10009584246 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4451** | click or scan EU-EC-10009584245 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4452** | click or scan EU-EC-10009584244 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4453** | click or scan EU-EC-10009584243 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4454** | click or scan EU-EC-10009584242 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4455** | click or scan EU-EC-10009584241 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4456** | click or scan EU-EC-10009584240 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4457** | click or scan EU-EC-10009584239 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4458** | click or scan EU-EC-10009584238 | | 2021-08-04 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4459** | click or scan EU-EC-10009584237 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4460** | click or scan EU-EC-10009584236 | | 2021-08-04 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4461** | click or scan EU-EC-10009584163 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| **4462** | click or scan EU-EC-10009584063 | | 2021-08-04 | Non Healthcare Professional | EEA | Not Specified | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4463** | click or scan EU-EC-10009583914 | | 2021-08-04 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Atrial flutter (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4464** | click or scan EU-EC-10009583133 | | 2021-08-04 | Healthcare Professional | EEA | 18-64 Years | Male | Blood pressure increased (0d - Fatal - **Results in Death**), Sudden death (0d - Fatal - **Results in Death**), Vomiting (0d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **4465** | click or scan EU-EC-10009583004 | | 2021-08-04 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Anaphylactic shock (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4466** | click or scan EU-EC-10009581080 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Male | Balance disorder (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Muscular weakness (n/a - Fatal - **Results in Death**), Paraesthesia (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4467** | click or scan EU-EC-10009581070 | | 2021-08-04 | Non Healthcare Professional | EEA | 65-85 Years | Female | Lymphadenopathy (88d - Fatal - **Results in Death**), Oropharyngeal pain (88d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4468** | click or scan EU-EC-10009582537 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Hypotension (n/a - Fatal - **Results in Death**), Oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4469** | click or scan EU-EC-10009582137 | | 2021-08-03 | Non Healthcare Professional | EEA | Not Specified | Male | COVID-19 (1d - Fatal - **Results in Death**) | [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a]) |
| **4470** | click or scan EU-EC-10009581859 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Ruptured cerebral aneurysm (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4471** | click or scan EU-EC-10009581424 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4472** | click or scan EU-EC-10009580541 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4473** | click or scan EU-EC-10009580436 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4474** | click or scan EU-EC-10009580238 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4475** | click or scan EU-EC-10009579767 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4476** | click or scan EU-EC-10009579666 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4477** | click or scan EU-EC-10009579181 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4478** | click or scan EU-EC-10009579178 | | 2021-08-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4479** | click or scan EU-EC-10009579175 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Constipation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cyanosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dehydration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Enterobacter infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flushing (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4480** | click or scan EU-EC-10009579169 | | 2021-08-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Disease recurrence (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4481** | click or scan EU-EC-10009579060 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **4482** | click or scan EU-EC-10009577919 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4483** | click or scan EU-EC-10009577882 | | 2021-08-03 | Non Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **4484** | click or scan EU-EC-10009577827 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4485** | click or scan EU-EC-10009577824 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4486** | click or scan EU-EC-10009577817 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Cardio-respiratory arrest (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| **4487** | click or scan EU-EC-10009577772 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4488** | click or scan EU-EC-10009577720 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Diarrhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Haemolytic anaemia (n/a - Fatal - **Results in Death**), Influenza like illness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4489** | click or scan EU-EC-10009577716 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | COVID-19 (1d - Fatal - **Results in Death**), Vaccination failure (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - n/a - Intramuscular]) |
| **4490** | click or scan EU-EC-10009577704 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Vaccination failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) |
| **4491** | click or scan EU-EC-10009577678 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4492** | click or scan EU-EC-10009577675 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4493** | click or scan EU-EC-10009577643 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4494** | click or scan EU-EC-10009577440 | | 2021-08-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Fall (n/a - Unknown - Other Medically Important Condition), Hip fracture (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Thrombosis (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4495** | click or scan EU-EC-10009577140 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4496** | click or scan EU-EC-10009576729 | | 2021-08-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hypoaesthesia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4497** | click or scan EU-EC-10009576724 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vaccination site haemorrhage (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4498** | click or scan EU-EC-10009576715 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Muscle rigidity (n/a - Unknown - Other Medically Important Condition), Pyelonephritis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4499** | click or scan EU-EC-10009576190 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Agonal rhythm (62d - Fatal - **Results in Death**), Asthenia (62d - Fatal - **Results in Death**), Cardiac arrest (62d - Fatal - **Results in Death**), Death (62d - Fatal - **Results in Death**), Dyspnoea (62d - Fatal - **Results in Death**), Endotracheal intubation (62d - Fatal - **Results in Death**), Feeling cold (62d - Fatal - **Results in Death**), Oedema peripheral (62d - Fatal - **Results in Death**), Oxygen saturation decreased (62d - Fatal - **Results in Death**), Rash macular (62d - Fatal - **Results in Death**), Respiratory disorder (62d - Fatal - **Results in Death**), Syncope (62d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4500** | click or scan EU-EC-10009576077 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4501** | click or scan EU-EC-10009576063 | | 2021-08-03 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Neurological symptom (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4502** | click or scan EU-EC-10009576056 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Bone contusion (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Monoplegia (n/a - Fatal - **Results in Death**), Musculoskeletal chest pain (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular]) |
| **4503** | click or scan EU-EC-10009576054 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cold sweat (n/a - Unknown - ), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory rate increased (n/a - Unknown - ), Restlessness (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4504** | click or scan EU-EC-10009576049 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4505** | click or scan EU-EC-10009576047 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Not Specified | Interstitial lung disease (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4506** | click or scan EU-EC-10009576036 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4507** | click or scan EU-EC-10009576034 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Unknown - ), Physical deconditioning (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4508** | click or scan EU-EC-10009576023 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4509** | click or scan EU-EC-10009575912 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agonal respiration (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - ), Heart rate decreased (n/a - Unknown - ), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pallor (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4510** | click or scan EU-EC-10009575910 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4511** | click or scan EU-EC-10009575896 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Blood pressure fluctuation (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mouth breathing (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pupillary reflex impaired (n/a - Unknown - Other Medically Important Condition), Pupils unequal (n/a - Unknown - Other Medically Important Condition), Pyelonephritis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**), Skin discolouration (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4512** | click or scan EU-EC-10009575622 | | 2021-08-03 | Healthcare Professional | EEA | Not Specified | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4513** | click or scan EU-EC-10009575561 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4514** | click or scan EU-EC-10009575524 | | 2021-08-03 | Healthcare Professional | EEA | More than 85 Years | Female | Acute kidney injury (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (19d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4515** | click or scan EU-EC-10009575376 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4516** | click or scan EU-EC-10009574769 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Organising pneumonia (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Pulmonary haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **4517** | click or scan EU-EC-10009574571 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Posture abnormal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4518** | click or scan EU-EC-10009574565 | | 2021-08-03 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4519** | click or scan EU-EC-10009574559 | | 2021-08-03 | Healthcare Professional | Non EEA | Not Specified | Male | Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4520** | click or scan EU-EC-10009574507 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4521** | click or scan EU-EC-10009574332 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4522** | click or scan EU-EC-10009574247 | | 2021-08-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Blood sodium decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Central nervous system infection (n/a - Fatal - **Results in Death**), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Encephalopathy (n/a - Fatal - **Results in Death**), Epilepsy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eyelid ptosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), General physical condition abnormal (n/a - Fatal - **Results in Death**, Disabling, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hyperhidrosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypersomnia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Memory impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Retroperitoneal haematoma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tenderness (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4523** | click or scan EU-EC-10009574237 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4524** | click or scan EU-EC-10009574232 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Dyspnoea (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4525** | click or scan EU-EC-10009573773 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4526** | click or scan EU-EC-10009573654 | | 2021-08-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Body mass index abnormal (n/a - Unknown - ), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4527** | click or scan EU-EC-10009573640 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cold sweat (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - ), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4528** | click or scan EU-EC-10009573472 | | 2021-08-03 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4529** | click or scan EU-EC-10009573267 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Constipation (n/a - Unknown - ), Loss of consciousness (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4530** | click or scan EU-EC-10009573261 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Female | Body temperature increased (n/a - Fatal - **Results in Death**, Life Threatening), COVID-19 (n/a - Fatal - **Results in Death**, Life Threatening), Crepitations (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - **Results in Death**, Life Threatening), Food refusal (n/a - Fatal - **Results in Death**, Life Threatening), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening), Tachycardia (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4531** | click or scan EU-EC-10009573215 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4532** | click or scan EU-EC-10009573141 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4533** | click or scan EU-EC-10009573029 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |
| **4534** | click or scan EU-EC-10009572770 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Myocarditis (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4535** | click or scan EU-EC-10009572379 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Unknown]) |
| **4536** | click or scan EU-EC-10009572186 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Female | Fatigue (n/a - Not Recovered/Not Resolved - ), Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) - DISPERSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **4537** | click or scan EU-EC-10009572090 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ), Heat illness (n/a - Unknown - ), Left ventricular failure (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4538** | click or scan EU-EC-10009571976 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4539** | click or scan EU-EC-10009571949 | | 2021-08-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Choking (n/a - Fatal - **Results in Death**), Fatigue (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4540** | click or scan EU-EC-10009571702 | | 2021-08-03 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA SUSPENSION FOR INJECTION COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4541** | click or scan EU-EC-10009571626 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Altered state of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Basilar artery occlusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Brain stem infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neck pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neuropathy peripheral (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4542** | click or scan EU-EC-10009571596 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute abdomen (n/a - Fatal - **Results in Death**), Chest discomfort (1d - Recovered/Resolved - ), Decreased appetite (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Haematochezia (n/a - Unknown - Other Medically Important Condition), Mesenteric arterial occlusion (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Unknown - ), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4543** | click or scan EU-EC-10009571448 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Arrhythmia (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - ), Nausea (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4544** | click or scan EU-EC-10009571446 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4545** | click or scan EU-EC-10009571438 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Male | Feeling hot (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4546** | click or scan EU-EC-10009571434 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**), Drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4547** | click or scan EU-EC-10009571395 | | 2021-08-03 | Non Healthcare Professional | EEA | 65-85 Years | Female | Acute coronary syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac valve disease (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4548** | click or scan EU-EC-10009571370 | | 2021-08-03 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Headache (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4549** | click or scan EU-EC-10009571324 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Carotid artery stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4550** | click or scan EU-EC-10009571302 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4551** | click or scan EU-EC-10009571299 | | 2021-08-03 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cheyne-Stokes respiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hemiparesis (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4552** | click or scan EU-EC-10009571114 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Colitis ischaemic (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4553** | click or scan EU-EC-10009571038 | | 2021-08-03 | Healthcare Professional | Non EEA | 18-64 Years | Male | Acute lymphocytic leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4554** | click or scan EU-EC-10009570527 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **4555** | click or scan EU-EC-10009570497 | | 2021-08-03 | Non Healthcare Professional | EEA | More than 85 Years | Female | Herpes zoster (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4556** | click or scan EU-EC-10009570496 | | 2021-08-03 | Healthcare Professional | EEA | 18-64 Years | Male | Acute coronary syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4557** | click or scan EU-EC-10009570409 | | 2021-08-03 | Healthcare Professional | EEA | 65-85 Years | Male | Acute coronary syndrome (53d - Fatal - **Results in Death**), Acute kidney injury (53d - Fatal - **Results in Death**), Haemorrhage (53d - Fatal - **Results in Death**), Ischaemic stroke (53d - Fatal - **Results in Death**), Pancreatic infarction (53d - Fatal - **Results in Death**), Pulmonary embolism (53d - Fatal - **Results in Death**), Thrombocytopenia (53d - Fatal - **Results in Death**), Venous thrombosis limb (53d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **4558** | click or scan EU-EC-10009569569 | | 2021-08-03 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute myocardial infarction (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **4559** | click or scan EU-EC-10009569147 | | 2021-08-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) |
| **4560** | click or scan EU-EC-10009568481 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (1d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4561** | click or scan EU-EC-10009567851 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4562** | click or scan EU-EC-10009567335 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4563** | click or scan EU-EC-10009567161 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asthma (n/a - Unknown - ), Cardiac failure acute (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - ), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4564** | click or scan EU-EC-10009567146 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cold sweat (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4565** | click or scan EU-EC-10009567127 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4566** | click or scan EU-EC-10009566801 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Body temperature increased (n/a - Fatal - **Results in Death**), Chills (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), General physical health deterioration (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Lung disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Seizure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Seizure like phenomena (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4567** | click or scan EU-EC-10009566703 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Bronchiectasis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Mycobacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pseudomonas infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) |
| **4568** | click or scan EU-EC-10009566628 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cellulitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling hot (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral circulatory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4569** | click or scan EU-EC-10009566566 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4570** | click or scan EU-EC-10009566476 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4571** | click or scan EU-EC-10009566437 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4572** | click or scan EU-EC-10009566397 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - ), Heat illness (n/a - Unknown - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4573** | click or scan EU-EC-10009566332 | | 2021-08-02 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4574** | click or scan EU-EC-10009566317 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Pulmonary embolism (0d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular]) |
| **4575** | click or scan EU-EC-10009565780 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Back pain (n/a - Unknown - ), Decreased appetite (n/a - Unknown - ), Dysstasia (n/a - Unknown - ), Infection (n/a - Fatal - **Results in Death**), Mobility decreased (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4576** | click or scan EU-EC-10009565509 | | 2021-08-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Dysphagia (n/a - Fatal - **Results in Death**), Tongue oedema (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4577** | click or scan EU-EC-10009565223 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Asthenia (3d - Recovered/Resolved - ), COVID-19 (18d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cavernous sinus thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Mucormycosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain (2d - Recovered/Resolved - ), Pulmonary fibrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4578** | click or scan EU-EC-10009565103 | | 2021-08-02 | Healthcare Professional | EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**), Venous oxygen saturation decreased (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1 {DF} - Intramuscular]) |
| **4579** | click or scan EU-EC-10009565076 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4580** | click or scan EU-EC-10009565064 | | 2021-08-02 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cough (9d - Fatal - **Results in Death**), Dyspnoea (5d - Fatal - **Results in Death**), Pneumonia (5d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4581** | click or scan EU-EC-10009564668 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (18d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (18d - Fatal - **Results in Death**), Pain (18d - Fatal - **Results in Death**), Pain in extremity (18d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **4582** | click or scan EU-EC-10009564637 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Aggression (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea exertional (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myalgia (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pain (128d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4583** | click or scan EU-EC-10009564198 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | COVID-19 pneumonia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (25d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4584** | click or scan EU-EC-10009564173 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Feeling abnormal (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**), Respiratory rate decreased (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4585** | click or scan EU-EC-10009564042 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **4586** | click or scan EU-EC-10009563935 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic dissection (n/a - Fatal - **Results in Death**), Chest injury (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Pericardial effusion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4587** | click or scan EU-EC-10009563857 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dementia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4588** | click or scan EU-EC-10009563799 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Vomiting (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4589** | click or scan EU-EC-10009563665 | | 2021-08-02 | Non Healthcare Professional | EEA | Not Specified | Male | Bundle branch block bilateral (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma hepatic (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatorenal syndrome (n/a - Unknown - Other Medically Important Condition), Hyperuricaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peritonitis bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Varices oesophageal (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4590** | click or scan EU-EC-10009563658 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Aortic stenosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), International normalised ratio increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4591** | click or scan EU-EC-10009563652 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Adrenal insufficiency (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4592** | click or scan EU-EC-10009563537 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Agitation (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Blood glucose increased (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dysarthria (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling of body temperature change (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hallucination (2d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Illness (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Insomnia (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Nausea (4d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (3d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4593** | click or scan EU-EC-10009563438 | | 2021-08-02 | Non Healthcare Professional | Non EEA | Not Specified | Male | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4594** | click or scan EU-EC-10009563433 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Acute myocardial infarction (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4595** | click or scan EU-EC-10009563335 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Renal failure (69d - Fatal - **Results in Death**, Other Medically Important Condition), Renal tubular necrosis (69d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4596** | click or scan EU-EC-10009562983 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (1d - Fatal - **Results in Death**, Other Medically Important Condition), Chills (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pain (1d - Fatal - **Results in Death**), Pyrexia (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **4597** | click or scan EU-EC-10009562930 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial aneurysm (50d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **4598** | click or scan EU-EC-10009562770 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Decreased appetite (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pollakiuria (n/a - Fatal - **Results in Death**), Toothache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4599** | click or scan EU-EC-10009562752 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Biliary sepsis (n/a - Fatal - **Results in Death**), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - n/a]) |
| **4600** | click or scan EU-EC-10009562624 | | 2021-08-02 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4601** | click or scan EU-EC-10009562492 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Body temperature increased (3d - Recovered/Resolved - Other Medically Important Condition), Cardiac failure acute (n/a - Fatal - **Results in Death**), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tonsillar hypertrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4602** | click or scan EU-EC-10009562434 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4603** | click or scan EU-EC-10009562391 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4604** | click or scan EU-EC-10009561754 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebellar infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4605** | click or scan EU-EC-10009561561 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Chest pain (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4606** | click or scan EU-EC-10009561450 | | 2021-08-02 | Healthcare Professional | EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**), Gastrointestinal disorder (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4607** | click or scan EU-EC-10009561242 | | 2021-08-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4608** | click or scan EU-EC-10009561197 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Female | Cavernous sinus thrombosis (n/a - Fatal - **Results in Death**), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4609** | click or scan EU-EC-10009561153 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4610** | click or scan EU-EC-10009561006 | | 2021-08-02 | Healthcare Professional | EEA | 18-64 Years | Female | Myocarditis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4611** | click or scan EU-EC-10009560837 | | 2021-08-02 | Non Healthcare Professional | EEA | 65-85 Years | Male | Fatigue (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4612** | click or scan EU-EC-10009560647 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Altered state of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Brain stem haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4613** | click or scan EU-EC-10009560637 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiogenic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4614** | click or scan EU-EC-10009560630 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), White blood cell count increased (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4615** | click or scan EU-EC-10009560535 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4616** | click or scan EU-EC-10009560534 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Abdominal pain upper (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Aortic thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Intestinal ischaemia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Neutrophilia (n/a - Unknown - Caused/Prolonged Hospitalisation), Platelet anisocytosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Splenic infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Splenic thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thrombosis mesenteric vessel (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4617** | click or scan EU-EC-10009560468 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Male | Brain stem haemorrhage (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4618** | click or scan EU-EC-10009559971 | | 2021-08-02 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4619** | click or scan EU-EC-10009559933 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Abdominal pain (8d - Unknown - ), Asthenia (8d - Not Recovered/Not Resolved - ), Atrial fibrillation (7d - Not Recovered/Not Resolved - ), COVID-19 pneumonia (7d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (8d - Unknown - ), Headache (9d - Unknown - ), Hypotension (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [5s - 1 {DF} - Intramuscular]) |
| **4620** | click or scan EU-EC-10009559778 | | 2021-08-02 | Healthcare Professional | EEA | More than 85 Years | Female | Atrial fibrillation (n/a - Fatal - **Results in Death**), Cardiac failure (n/a - Fatal - **Results in Death**), Cardiac failure chronic (n/a - Fatal - **Results in Death**), Circulatory collapse (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4621** | click or scan EU-EC-10009559769 | | 2021-08-02 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Deep vein thrombosis (n/a - Fatal - **Results in Death**), Immune thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4622** | click or scan EU-EC-10009559632 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Chest pain (n/a - Unknown - ), Malaise (n/a - Unknown - ), Muscular weakness (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4623** | click or scan EU-EC-10009559599 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Disseminated intravascular coagulation (n/a - Unknown - Other Medically Important Condition), Hepatic necrosis (n/a - Unknown - Other Medically Important Condition), Intestinal ischaemia (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pyelonephritis acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal graft infection (n/a - Unknown - Other Medically Important Condition), Septic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenic infection (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4624** | click or scan EU-EC-10009559507 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Loss of consciousness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **4625** | click or scan EU-EC-10009558818 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral artery embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4626** | click or scan EU-EC-10009558793 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4627** | click or scan EU-EC-10009558727 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Condition aggravated (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dehydration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4628** | click or scan EU-EC-10009558629 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Confusional state (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1 {DF} - Intramuscular]) |
| **4629** | click or scan EU-EC-10009558474 | | 2021-08-02 | Healthcare Professional | Non EEA | More than 85 Years | Female | Blood pressure increased (n/a - Unknown - ), Cardiac hypertrophy (n/a - Unknown - ), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vascular occlusion (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4630** | click or scan EU-EC-10009558467 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Female | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Endocarditis noninfective (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Heart injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Intracardiac thrombus (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4631** | click or scan EU-EC-10009558149 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Dehydration (n/a - Unknown - Other Medically Important Condition), Visual acuity reduced (2d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4632** | click or scan EU-EC-10009557861 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Ageusia (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Nasopharyngitis (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4633** | click or scan EU-EC-10009557750 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4634** | click or scan EU-EC-10009557715 | | 2021-08-02 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Dose not changed - [n/a - n/a - Intramuscular]) |
| **4635** | click or scan EU-EC-10009557714 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Male | Unresponsive to stimuli (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4636** | click or scan EU-EC-10009557713 | | 2021-08-02 | Healthcare Professional | Non EEA | 65-85 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4637** | click or scan EU-EC-10009556468 | | 2021-07-31 | Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) |
| **4638** | click or scan EU-EC-10009555729 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Neoplasm malignant (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **4639** | click or scan EU-EC-10009555626 | | 2021-07-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | COVID-19 (10d - Fatal - **Results in Death**), Thrombosis (n/a - Recovering/Resolving - **Results in Death**), Vaccination failure (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4640** | click or scan<br>EU-EC-10009555608 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Arthralgia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cold sweat (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Food refusal (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate decreased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maximum heart rate increased (n/a - Recovering/Resolving - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4641** | click or scan<br>EU-EC-10009555604 | | 2021-07-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Decubitus ulcer (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Inflammatory marker increased (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Vaccination error (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4642** | click or scan<br>EU-EC-10009555581 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Blood lactic acid increased (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Brain hypoxia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Cardiac arrest (n/a - Recovered/Resolved - **Results in Death**, Other Medically Important Condition), Ischaemia (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Vasculitis (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4643** | click or scan<br>EU-EC-10009555413 | | 2021-07-31 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Abdominal distension (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Abdominal pain upper (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Amnesia (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Anger (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Aortic stenosis (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Delusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Dementia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Hyperventilation (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling), Peripheral swelling (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4644** | click or scan<br>EU-EC-10009555408 | | 2021-07-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute left ventricular failure (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Arrhythmia (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiac failure acute (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4645** | click or scan<br>EU-EC-10009555405 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Giant cell arteritis (n/a - Unknown - **Results in Death**), Intracardiac thrombus (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4646** | click or scan EU-EC-10009555383 | | 2021-07-31 | Healthcare Professional | Non EEA | More than 85 Years | Female | Dyspnoea (n/a - Not Recovered/Not Resolved - **Results in Death**), Folate deficiency (n/a - Unknown - **Results in Death**), Haemoptysis (n/a - Not Recovered/Not Resolved - **Results in Death**), Haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**), Iron deficiency (n/a - Unknown - **Results in Death**), Normocytic anaemia (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Not Recovered/Not Resolved - **Results in Death**), Thrombocytopenia (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - n/a]) |
| **4647** | click or scan EU-EC-10009555329 | | 2021-07-31 | Non Healthcare Professional | Non EEA | Not Specified | Male | Death (n/a - Fatal - **Results in Death**, Life Threatening, Disabling) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - n/a]) |
| **4648** | click or scan EU-EC-10009555260 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Epistaxis (n/a - Not Recovered/Not Resolved - **Results in Death**), Hepatic failure (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Unknown - [n/a - n/a - n/a]) |
| **4649** | click or scan EU-EC-10009555201 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood urine (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Device occlusion (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Disease progression (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage urinary tract (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - n/a]) |
| **4650** | click or scan EU-EC-10009555060 | | 2021-07-31 | Healthcare Professional | Non EEA | 65-85 Years | Female | Acute respiratory failure (n/a - Fatal - **Results in Death**, Life Threatening), Dyspnoea (n/a - Unknown - **Results in Death**, Life Threatening), Pneumonia (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4651** | click or scan EU-EC-10009555059 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Agitation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Aphasia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Brain injury (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chest pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Coma scale abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Disorientation (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial pressure increased (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pupillary light reflex tests abnormal (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4652** | click or scan EU-EC-10009555047 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - n/a]) |
| **4653** | click or scan EU-EC-10009555046 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Abdominal pain (n/a - Unknown - **Results in Death**), Activated partial thromboplastin time prolonged (n/a - Unknown - **Results in Death**), Embolism (n/a - Unknown - **Results in Death**), Intestinal ischaemia (n/a - Unknown - **Results in Death**), Multiple organ dysfunction syndrome (n/a - Unknown - **Results in Death**), Thrombocytopenia (n/a - Unknown - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S- n/a - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4654** | click or scan EU-EC-10009555040 | | 2021-07-31 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arthralgia (9d - Not Recovered/Not Resolved - **Results in Death**), Cardiac arrest (n/a - Not Recovered/Not Resolved - **Results in Death**), Inflammation (n/a - Not Recovered/Not Resolved - **Results in Death**), Influenza like illness (13d - Not Recovered/Not Resolved - **Results in Death**), Lower respiratory tract infection (9d - Not Recovered/Not Resolved - **Results in Death**), Myalgia (9d - Not Recovered/Not Resolved - **Results in Death**), Pyrexia (13d - Not Recovered/Not Resolved - **Results in Death**), Vasculitic rash (n/a - Not Recovered/Not Resolved - **Results in Death**), Vasculitis (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4655** | click or scan EU-EC-10009554961 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Not Recovered/Not Resolved - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4656** | click or scan EU-EC-10009554960 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Headache (n/a - Unknown - **Results in Death**), Influenza like illness (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **4657** | click or scan EU-EC-10009554606 | | 2021-07-31 | Non Healthcare Professional | Non EEA | Not Specified | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]) |
| **4658** | click or scan EU-EC-10009554425 | | 2021-07-31 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Anxiety (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Death (23d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Fatigue (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Feeling abnormal (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Incontinence (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4659** | click or scan EU-EC-10009554418 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chest pain (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Hyperhidrosis (n/a - Unknown - **Results in Death**), Myocardial ischaemia (n/a - Fatal - **Results in Death**), Palpitations (n/a - Unknown - **Results in Death**), Sleep disorder (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [1d - n/a - n/a]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |
| **4660** | click or scan EU-EC-10009554396 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Atrial fibrillation (n/a - Unknown - **Results in Death**), Cardiac failure congestive (n/a - Unknown - **Results in Death**), Dizziness (n/a - Unknown - **Results in Death**), Dyspnoea (n/a - Unknown - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4661** | click or scan<br>EU-EC-10009554392 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Abdominal pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arterial thrombosis (n/a - Not Recovered/Not Resolved - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral venous sinus thrombosis (6d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flank pain (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematuria (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoptysis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nephrolithiasis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oral contusion (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral ischaemia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Portal vein thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyelonephritis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic thrombosis (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4662** | click or scan<br>EU-EC-10009554390 | | 2021-07-31 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Loss of consciousness (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pleural effusion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4663** | click or scan<br>EU-EC-10009553829 | | 2021-07-31 | Healthcare Professional | EEA | 65-85 Years | Male | Ascites (86d - Fatal - **Results in Death**), Colon cancer (86d - Fatal - **Results in Death**), Lymphadenopathy (86d - Fatal - **Results in Death**), Metastases to liver (86d - Fatal - **Results in Death**), Metastases to lung (86d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .5mL - Intramuscular]) |
| **4664** | click or scan<br>EU-EC-10009553763 | | 2021-07-31 | Healthcare Professional | EEA | More than 85 Years | Male | Respiratory failure (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 1 {DF} - Intramuscular]) |
| **4665** | click or scan<br>EU-EC-10009553745 | | 2021-07-31 | Healthcare Professional | EEA | 18-64 Years | Female | Cardiac arrest (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4666** | click or scan EU-EC-10009552923 | | 2021-07-31 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4667** | click or scan EU-EC-10009552869 | | 2021-07-31 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4668** | click or scan EU-EC-10009552322 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Aortic rupture (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Fall (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4669** | click or scan EU-EC-10009552277 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (2d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4670** | click or scan EU-EC-10009551941 | | 2021-07-30 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | COVID-19 (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4671** | click or scan EU-EC-10009551698 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Angioimmunoblastic T-cell lymphoma (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Condition aggravated (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tubulointerstitial nephritis (55d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [2d - n/a - Intramuscular]) |
| **4672** | click or scan EU-EC-10009551640 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Female | Capillary leak syndrome (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4673** | click or scan EU-EC-10009551392 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Intestinal ischaemia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4674** | click or scan EU-EC-10009551194 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4675** | click or scan EU-EC-10009550661 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4676** | click or scan EU-EC-10009550584 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4677** | click or scan EU-EC-10009550522 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Catastrophic reaction (2d - Fatal - **Results in Death**), Cerebrovascular accident (2d - Fatal - **Results in Death**, Other Medically Important Condition), Death (2d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4678** | click or scan EU-EC-10009550235 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4679** | click or scan EU-EC-10009549456 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Oedema (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4680** | click or scan EU-EC-10009549444 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal pain (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Decreased appetite (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dizziness (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Neck mass (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4681** | click or scan EU-EC-10009549392 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Hyperpyrexia (n/a - Fatal - **Results in Death**), Injection site pain (2d - Recovered/Resolved - ), Injection site pruritus (2d - Recovered/Resolved - ), Malaise (n/a - Fatal - **Results in Death**), Myalgia (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Restlessness (n/a - Fatal - **Results in Death**), Sepsis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4682** | click or scan EU-EC-10009549354 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Malaise (n/a - Recovered/Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Recovered/Resolved - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4683** | click or scan EU-EC-10009549246 | | 2021-07-30 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal distension (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal distension (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed mood (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - ), Non-Hodgkin's lymphoma (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4684** | click or scan EU-EC-10009548680 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Venous thrombosis limb (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4685** | click or scan EU-EC-10009548347 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chronic obstructive pulmonary disease (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Dysuria (n/a - Fatal - **Results in Death**), Pain (n/a - Fatal - **Results in Death**), Respiratory distress (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Somnolence (n/a - Fatal - **Results in Death**), Wheezing (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4686** | click or scan EU-EC-10009548241 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Apnoea (n/a - Fatal - **Results in Death**), Hypophagia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - ), Respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4687** | click or scan EU-EC-10009548173 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Female | Cardiac failure (n/a - Fatal - **Results in Death**), Oedema peripheral (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4688** | click or scan EU-EC-10009547783 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Adverse event following immunisation (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4689** | click or scan EU-EC-10009547512 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4690** | click or scan EU-EC-10009547487 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Ischaemic stroke (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4691** | click or scan EU-EC-10009547454 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Creutzfeldt-Jakob disease (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4692** | click or scan EU-EC-10009547414 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) |
| **4693** | click or scan EU-EC-10009547294 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) |
| **4694** | click or scan EU-EC-10009547286 | | 2021-07-30 | Healthcare Professional | EEA | More than 85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4695** | click or scan EU-EC-10009547001 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Cough (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4696** | click or scan EU-EC-10009546788 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Musculoskeletal discomfort (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4697** | click or scan EU-EC-10009546759 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Female | Malaise (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4698** | click or scan EU-EC-10009546137 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4699** | click or scan EU-EC-10009546136 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Near drowning (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4700** | click or scan EU-EC-10009546071 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardiac failure acute (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Foaming at mouth (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4701** | click or scan EU-EC-10009545930 | | 2021-07-30 | Healthcare Professional | EEA | More than 85 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4702** | click or scan EU-EC-10009545767 | | 2021-07-30 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Arteriosclerosis (n/a - Unknown - Other Medically Important Condition), Congestive hepatopathy (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Productive cough (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4703** | click or scan EU-EC-10009545667 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**), Vaccination site pain (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4704** | click or scan EU-EC-10009545572 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4705** | click or scan EU-EC-10009545479 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **4706** | click or scan EU-EC-10009544851 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Female | Left ventricular failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4707** | click or scan EU-EC-10009544795 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Female | Chest pain (n/a - Not Recovered/Not Resolved - ), Circulatory collapse (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4708** | click or scan EU-EC-10009544209 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Male | Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4709** | click or scan EU-EC-10009544170 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4710** | click or scan EU-EC-10009544138 | | 2021-07-30 | Healthcare Professional | EEA | 18-64 Years | Male | Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4711** | click or scan EU-EC-10009544103 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4712** | click or scan EU-EC-10009544100 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Not Specified | Cardiac arrest (n/a - Fatal - **Results in Death**), Vomiting (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4713** | click or scan EU-EC-10009544097 | | 2021-07-30 | Non Healthcare Professional | EEA | More than 85 Years | Female | Capillary leak syndrome (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Taste disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4714** | click or scan EU-EC-10009544094 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4715** | click or scan EU-EC-10009543811 | | 2021-07-30 | Non Healthcare Professional | EEA | 18-64 Years | Male | Back pain (n/a - Fatal - **Results in Death**), COVID-19 immunisation (n/a - Fatal - **Results in Death**), Dysgeusia (n/a - Fatal - **Results in Death**), Feeling cold (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Unresponsive to stimuli (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) |
| **4716** | click or scan EU-EC-10009543795 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Coronary artery disease (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fall (n/a - Fatal - **Results in Death**), Hypopnoea (n/a - Fatal - **Results in Death**), Increased upper airway secretion (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4717** | click or scan EU-EC-10009543540 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Pyrexia (11h - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4718** | click or scan EU-EC-10009543446 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cerebral haematoma (n/a - Unknown - Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cerebral ventricular rupture (n/a - Unknown - Other Medically Important Condition), Dysarthria (n/a - Unknown - ), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4719** | click or scan EU-EC-10009542412 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) |
| **4720** | click or scan EU-EC-10009542033 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4721** | click or scan EU-EC-10009541941 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Altered state of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4722** | click or scan EU-EC-10009541398 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Haematemesis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Interstitial lung disease (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary alveolar haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4723** | click or scan EU-EC-10009541252 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Anaemia (n/a - Unknown - ), Asthenia (n/a - Unknown - ), Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - ), Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**), Delirium (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Unknown - ), Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Ventricular extrasystoles (n/a - Unknown - ), White blood cell count decreased (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4724** | click or scan EU-EC-10009541000 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthma (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4725** | click or scan EU-EC-10009540998 | | 2021-07-30 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4726** | click or scan EU-EC-10009540761 | | 2021-07-30 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Herpes zoster (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4727** | click or scan EU-EC-10009540464 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4728** | click or scan EU-EC-10009540115 | | 2021-07-30 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute leukaemia (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Leukaemia (n/a - Fatal - **Results in Death**), Motor dysfunction (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Pain in extremity (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Speech disorder (n/a - Fatal - **Results in Death**), Tremor (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **4729** | click or scan EU-EC-10009539778 | | 2021-07-30 | Healthcare Professional | EEA | 65-85 Years | Female | Arthralgia (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **4730** | click or scan EU-EC-10009539502 | | 2021-07-30 | Healthcare Professional | Non EEA | 18-64 Years | Male | Respiratory failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4731** | click or scan EU-EC-10009612908 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Anaemia (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Anti-neutrophil cytoplasmic antibody positive vasculitis (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood disorder (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypophagia (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (72d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown - More in ICSR]) |
| **4732** | click or scan EU-EC-10009539030 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Renal failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4733** | click or scan EU-EC-10009538901 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Hypoxic-ischaemic encephalopathy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4734** | click or scan EU-EC-10009538127 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Male | Autoimmune hepatitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic cirrhosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Jaundice (n/a - Not Recovered/Not Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Pruritus (n/a - Recovered/Resolved - **Results in Death**, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4735** | click or scan EU-EC-10009538086 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Female | Sudden death (n/a - Fatal - **Results in Death**, Life Threatening) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4736** | click or scan EU-EC-10009538047 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4737** | click or scan EU-EC-10009537965 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Male | Atrial thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Subclavian vein thrombosis (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **4738** | click or scan EU-EC-10009537818 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Abdominal pain upper (56d - Fatal - **Results in Death**, Life Threatening, Disabling), Back pain (56d - Fatal - **Results in Death**, Life Threatening, Disabling), Blindness (56d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition), Pain (56d - Fatal - **Results in Death**, Life Threatening, Disabling), Plasma cell myeloma (56d - Fatal - **Results in Death**, Life Threatening, Disabling, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4739** | click or scan EU-EC-10009537803 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Female | Bacterial infection (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4740** | click or scan EU-EC-10009537679 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4741** | click or scan EU-EC-10009537575 | | 2021-07-29 | Non Healthcare Professional | Non EEA | Not Specified | Female | Acute promyelocytic leukaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Intracranial pressure increased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Platelet count decreased (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Skin haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4742** | click or scan EU-EC-10009537415 | | 2021-07-29 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal heart rate abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Foetal hypokinesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Low birth weight baby (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Stillbirth (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transplacental]) |
| **4743** | click or scan EU-EC-10009537405 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Incorrect route of product administration (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intravenous (not otherwise specified)]) |
| **4744** | click or scan EU-EC-10009536844 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4745** | click or scan EU-EC-10009536800 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4746** | click or scan EU-EC-10009536546 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Acute myeloid leukaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4747** | click or scan EU-EC-10009536428 | | 2021-07-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Unknown - **Results in Death**), Decreased appetite (n/a - Unknown - **Results in Death**), Feeling abnormal (n/a - Unknown - **Results in Death**), Gait disturbance (n/a - Unknown - **Results in Death**), Haematoma (n/a - Unknown - **Results in Death**), Hypersomnia (n/a - Unknown - **Results in Death**), Nervousness (n/a - Unknown - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**), Weight decreased (n/a - Unknown - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4748** | click or scan EU-EC-10009536337 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | COVID-19 (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4749** | click or scan EU-EC-10009536193 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Anaphylactic shock (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4750** | click or scan EU-EC-10009536115 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Brain stem haemorrhage (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Poor quality product administered (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4751** | click or scan EU-EC-10009536099 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myeloid leukaemia (n/a - Fatal - **Results in Death**), Atrial fibrillation (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**), Pneumonia (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Septic shock (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) |
| **4752** | click or scan EU-EC-10009535917 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) |
| **4753** | click or scan EU-EC-10009535755 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Abdominal discomfort (n/a - Unknown - ), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Constipation (n/a - Unknown - ), Cough (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dysphonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Unknown - ), Pain (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Unknown - ), Sensation of foreign body (n/a - Unknown - ), Sudden cardiac death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4754** | click or scan EU-EC-10009535654 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Decreased appetite (12d - Fatal - **Results in Death**), Fatigue (12d - Fatal - **Results in Death**), Headache (12d - Fatal - **Results in Death**), Vaccine positive rechallenge (12d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4755** | click or scan EU-EC-10009535576 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac hypertrophy (1d - Fatal - **Results in Death**), Deep vein thrombosis (1d - Fatal - **Results in Death**, Other Medically Important Condition), Fatigue (1d - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**), Prostate cancer (1d - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (1d - Fatal - **Results in Death**, Other Medically Important Condition), Sudden death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4756** | click or scan EU-EC-10009535521 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4757** | click or scan EU-EC-10009535296 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (S - Atrial fibrillation - Not applicable - [n/a - 20mg - n/a]) |
| **4758** | click or scan EU-EC-10009535288 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), XARELTO [RIVAROXABAN] (S - Atrial fibrillation - Not applicable - [n/a - 20mg - n/a]) |
| **4759** | click or scan EU-EC-10009535248 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Headache (n/a - Unknown - **Results in Death**, Other Medically Important Condition), Sudden death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Syncope (n/a - Unknown - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) |
| **4760** | click or scan EU-EC-10009534910 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4761** | click or scan EU-EC-10009534758 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Asthma (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a]) |
| **4762** | click or scan EU-EC-10009534616 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Not Specified | Death (n/a - Fatal - **Results in Death**), Head injury (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4763** | click or scan EU-EC-10009534609 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4764** | click or scan EU-EC-10009534607 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4765** | click or scan EU-EC-10009534601 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Circulatory collapse (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4766** | click or scan EU-EC-10009534476 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Vaccination complication (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4767** | click or scan EU-EC-10009534389 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4768** | click or scan EU-EC-10009534103 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4769** | click or scan EU-EC-10009534090 | | 2021-07-29 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4770** | click or scan EU-EC-10009533788 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Myositis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Spontaneous haematoma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4771** | click or scan EU-EC-10009533760 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Angioedema (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4772** | click or scan EU-EC-10009533753 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [1d - 1 {DF} - Intramuscular]) |
| **4773** | click or scan EU-EC-10009533719 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4774** | click or scan EU-EC-10009533718 | | 2021-07-29 | Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4775** | click or scan EU-EC-10009533717 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4776** | click or scan EU-EC-10009533709 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Male | Troponin abnormal (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |
| **4777** | click or scan EU-EC-10009533653 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4778** | click or scan EU-EC-10009533648 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Cardio-respiratory arrest (1d - Fatal - **Results in Death**), Pulseless electrical activity (1d - Fatal - **Results in Death**), Ventricular fibrillation (1d - Not Recovered/Not Resolved - Life Threatening) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) |
| **4779** | click or scan EU-EC-10009533625 | | 2021-07-29 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Bradycardia foetal (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **4780** | click or scan EU-EC-10009533595 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Chest pain (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Suicide attempt (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4781** | click or scan EU-EC-10009533565 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4782** | click or scan EU-EC-10009533412 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Poor quality product administered (n/a - Unknown - ) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular]) |
| **4783** | click or scan EU-EC-10009532960 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Abortion spontaneous (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4784** | click or scan EU-EC-10009532514 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Erythema (3d - Fatal - **Results in Death**), Nodule (3d - Fatal - **Results in Death**), Peripheral swelling (3d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4785** | click or scan EU-EC-10009532172 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Brain death (n/a - Fatal - **Results in Death**, Life Threatening), Cardiomegaly (n/a - Not Recovered/Not Resolved - Life Threatening), Cerebral haemorrhage (n/a - Unknown - Life Threatening), Coma (n/a - Unknown - Life Threatening), Hypertension (n/a - Unknown - Life Threatening), Thrombosis (n/a - Unknown - Life Threatening) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4786** | click or scan EU-EC-10009532162 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4787** | click or scan EU-EC-10009532011 | | 2021-07-29 | Non Healthcare Professional | Non EEA | More than 85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Haemorrhagic stroke (n/a - Fatal - **Results in Death**), Hypertension (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4788** | click or scan EU-EC-10009531981 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Gastrointestinal haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hepatitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Jaundice (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Lung neoplasm malignant (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pancreatitis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4789** | click or scan EU-EC-10009531962 | | 2021-07-29 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Fatal - **Results in Death**), Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Intracardiac thrombus (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Fatal - **Results in Death**), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - n/a]) |
| **4790** | click or scan EU-EC-10009531823 | | 2021-07-29 | Non Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4791** | click or scan EU-EC-10009531724 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial ischaemia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4792** | click or scan EU-EC-10009531669 | | 2021-07-29 | Healthcare Professional | EEA | 18-64 Years | Male | Myocarditis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4793** | click or scan EU-EC-10009531561 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Immune thrombocytopenia (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4794** | click or scan EU-EC-10009531545 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Male | Intestinal obstruction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Peritonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4795** | click or scan EU-EC-10009531540 | | 2021-07-29 | Healthcare Professional | Non EEA | More than 85 Years | Female | Lymphoproliferative disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial ischaemia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pancytopenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4796** | click or scan EU-EC-10009531537 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Aortic dissection (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Back pain (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4797** | click or scan EU-EC-10009531444 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Contusion (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition), Vascular dementia (n/a - Fatal - **Results in Death**, Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4798** | click or scan EU-EC-10009531268 | | 2021-07-29 | Non Healthcare Professional | EEA | 18-64 Years | Female | Body temperature increased (2d - Recovered/Resolved - ), Death (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - Not applicable - [n/a - .5mL - Intramuscular]) |
| **4799** | click or scan EU-EC-10009531246 | | 2021-07-29 | Healthcare Professional | Non EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular]) |
| **4800** | click or scan EU-EC-10009530470 | | 2021-07-29 | Healthcare Professional | EEA | Not Specified | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4801** | click or scan EU-EC-10009530376 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Autoimmune haemolytic anaemia (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dialysis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dizziness (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Fatigue (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Splenectomy (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Vomiting (97d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **4802** | click or scan EU-EC-10009530224 | | 2021-07-29 | Non Healthcare Professional | EEA | 65-85 Years | Male | Abdominal pain upper (2d - Fatal - **Results in Death**), Chills (2d - Fatal - **Results in Death**), Dyspnoea (2d - Fatal - **Results in Death**), Headache (2d - Fatal - **Results in Death**), Hypoaesthesia (2d - Fatal - **Results in Death**), Hypopnoea (2d - Fatal - **Results in Death**), Malaise (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4803** | click or scan EU-EC-10009529859 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Asthenia (n/a - Fatal - **Results in Death**), Dizziness (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Pallor (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4804** | click or scan EU-EC-10009529856 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Anger (n/a - Unknown - Caused/Prolonged Hospitalisation), Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Brain death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhagic stroke (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Illness (n/a - Unknown - Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mood swings (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - ), Ruptured cerebral aneurysm (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Strabismus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4805** | click or scan EU-EC-10009529847 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Marasmus (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) |
| **4806** | click or scan EU-EC-10009529845 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4807** | click or scan EU-EC-10009529831 | | 2021-07-29 | Non Healthcare Professional | Non EEA | More than 85 Years | Female | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4808** | click or scan EU-EC-10009529828 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Pyrexia (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4809** | click or scan EU-EC-10009529772 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4810** | click or scan EU-EC-10009529646 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Arrhythmia (n/a - Fatal - **Results in Death**), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4811** | click or scan EU-EC-10009528731 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Chills (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Dyspnoea (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular - More in ICSR]) |
| **4812** | click or scan EU-EC-10009528674 | | 2021-07-29 | Healthcare Professional | EEA | Not Specified | Female | Axillary vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening), Pulmonary embolism (n/a - Fatal - **Results in Death**, Life Threatening) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4813** | click or scan EU-EC-10009528415 | | 2021-07-29 | Healthcare Professional | Non EEA | Not Specified | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4814** | click or scan EU-EC-10009528277 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Adverse reaction (n/a - Unknown - ), Aortic valve disease (n/a - Unknown - ), Cardiac failure congestive (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Cyanosis (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Unknown - ), Feeling abnormal (n/a - Unknown - ), Gait disturbance (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Illness (n/a - Unknown - ), Insomnia (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Myocardial infarction (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - ), Pallor (n/a - Unknown - ), Paradoxical drug reaction (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - ), Pulmonary mass (n/a - Unknown - ), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - ), Suicidal ideation (n/a - Unknown - Other Medically Important Condition), Vaccination site erythema (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ), Vasodilatation (n/a - Unknown - ), Vomiting (n/a - Unknown - ) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4815** | click or scan EU-EC-10009528259 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Female | Flank pain (n/a - Fatal - **Results in Death**), Pyrexia (n/a - Fatal - **Results in Death**), Urine copper (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4816** | click or scan EU-EC-10009528228 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Female | Connective tissue disorder (n/a - Fatal - **Results in Death**), Disseminated intravascular coagulation (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Haemorrhagic disorder (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Myocarditis (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4817** | click or scan EU-EC-10009528207 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Pneumonia bacterial (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4818** | click or scan EU-EC-10009527573 | | 2021-07-29 | Healthcare Professional | Non EEA | 65-85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4819** | click or scan EU-EC-10009527318 | | 2021-07-29 | Non Healthcare Professional | Non EEA | Not Specified | Not Specified | Foetal death (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]) |
| **4820** | click or scan EU-EC-10009526900 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Blood pressure decreased (n/a - Unknown - ), COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - ) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4821** | click or scan EU-EC-10009526876 | | 2021-07-29 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cognitive disorder (n/a - Fatal - **Results in Death**), Concomitant disease aggravated (n/a - Fatal - **Results in Death**), Decreased appetite (n/a - Fatal - **Results in Death**), Inappropriate schedule of product administration (n/a - Unknown - ), Lethargy (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4822** | click or scan EU-EC-10009526856 | | 2021-07-29 | Non Healthcare Professional | Non EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4823** | click or scan EU-EC-10009526015 | | 2021-07-29 | Non Healthcare Professional | EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4824** | click or scan EU-EC-10009525478 | | 2021-07-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Male | Asthenia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Hypokinesia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Neuromyelitis optica spectrum disorder (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4825** | click or scan EU-EC-10009524720 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4826** | click or scan EU-EC-10009524690 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **4827** | click or scan EU-EC-10009524335 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Dyspnoea (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (20d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4828** | click or scan EU-EC-10009524319 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | ELIQUIS [APIXABAN] (S - n/a - n/a - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (S - n/a - n/a - [n/a - n/a - n/a]), [BENSERAZIDE, LEVODOPA] (S - n/a - n/a - [n/a - n/a - n/a]), [BIPERIDEN, BIPERIDEN HYDROCHLORIDE, BIPERIDEN LACTATE] (S - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (S - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (S - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4829** | click or scan EU-EC-10009524310 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Female | General physical health deterioration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Staphylococcal sepsis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4830** | click or scan EU-EC-10009524268 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4831** | click or scan EU-EC-10009524264 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Headache (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4832** | click or scan EU-EC-10009524259 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Anuria (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4833** | click or scan EU-EC-10009524256 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4834** | click or scan EU-EC-10009524240 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4835** | click or scan EU-EC-10009524232 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cardiac arrest (n/a - Fatal - **Results in Death**), Diarrhoea (n/a - Fatal - **Results in Death**), Nausea (n/a - Fatal - **Results in Death**), Palpitations (n/a - Fatal - **Results in Death**), Troponin increased (n/a - Fatal - **Results in Death**), Vomiting (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4836** | click or scan EU-EC-10009524231 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Movement disorder (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4837** | click or scan EU-EC-10009524202 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Male | Cerebrovascular accident (11d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (9d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4838** | click or scan EU-EC-10009524190 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4839** | click or scan EU-EC-10009524165 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Anaphylactic reaction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4840** | click or scan EU-EC-10009523869 | | 2021-07-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac disorder (1d - Fatal - **Results in Death**), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition), Heart rate irregular (1d - Fatal - **Results in Death**), Memory impairment (1d - Fatal - **Results in Death**), Sleep apnoea syndrome (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4841** | click or scan EU-EC-10009523797 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4842** | click or scan EU-EC-10009523794 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4843** | click or scan EU-EC-10009523784 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4844** | click or scan EU-EC-10009523624 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4845** | click or scan EU-EC-10009523566 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4846** | click or scan EU-EC-10009523499 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4847** | click or scan EU-EC-10009523490 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Female | Brain injury (5d - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4848** | click or scan EU-EC-10009523460 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4849** | click or scan EU-EC-10009522992 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea exertional (n/a - Unknown - ), Limb discomfort (n/a - Unknown - ), Nightmare (n/a - Unknown - ), Oedema (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4850** | click or scan EU-EC-10009522895 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Autoimmune haemolytic anaemia (8d - Fatal - **Results in Death**), Pulmonary embolism (8d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4851** | click or scan EU-EC-10009522781 | | 2021-07-28 | Healthcare Professional | Non EEA | Not Specified | Not Specified | Abortion induced (n/a - Fatal - **Results in Death**, Congenital Anomaly), Congenital nose malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Cytogenetic abnormality (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Limb malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Multiple congenital abnormalities (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4852** | click or scan EU-EC-10009522720 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Male | Guillain-Barre syndrome (n/a - Fatal - **Results in Death**), Paralysis (7d - Fatal - **Results in Death**), Respiratory failure (7d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4853** | click or scan EU-EC-10009522634 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4854** | click or scan EU-EC-10009522518 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Crush syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4855** | click or scan EU-EC-10009522508 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4856** | click or scan EU-EC-10009522403 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Brain oedema (n/a - Fatal - **Results in Death**), Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4857** | click or scan EU-EC-10009522375 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4858** | click or scan EU-EC-10009522286 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4859** | click or scan EU-EC-10009522245 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Female | Pemphigoid (5mo - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4860** | click or scan EU-EC-10009522201 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Asthenia (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4861** | click or scan EU-EC-10009522180 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Alveolitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Autoimmune disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4862** | click or scan EU-EC-10009522176 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Brain injury (n/a - Fatal - **Results in Death**), Cerebral venous sinus thrombosis (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4863** | click or scan EU-EC-10009521978 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden death (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - .5mL - Intramuscular]) |
| **4864** | click or scan EU-EC-10009521945 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **4865** | click or scan EU-EC-10009521901 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Acute respiratory distress syndrome (23d - Fatal - **Results in Death**), Lung infiltration (23d - Fatal - **Results in Death**), Lung transplant rejection (23d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4866** | click or scan EU-EC-10009521797 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Acute left ventricular failure (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Acute myocardial infarction (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (2d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4867** | click or scan EU-EC-10009521777 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4868** | click or scan EU-EC-10009521748 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Thrombosis (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4869** | click or scan EU-EC-10009521672 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4870** | click or scan EU-EC-10009521647 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4871** | click or scan EU-EC-10009521636 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4872** | click or scan EU-EC-10009521609 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Influenza like illness (2d - Fatal - **Results in Death**), Myalgia (2d - Fatal - **Results in Death**), Pyrexia (2d - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4873** | click or scan EU-EC-10009521292 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Fall (n/a - Fatal - **Results in Death**), Hypotension (n/a - Fatal - **Results in Death**), Syncope (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **4874** | click or scan EU-EC-10009521250 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4875** | click or scan EU-EC-10009521207 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Female | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Nausea (0d - Not Recovered/Not Resolved - ) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4876** | click or scan EU-EC-10009521155 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4877** | click or scan EU-EC-10009521107 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Death (n/a - Fatal - **Results in Death**), Pneumonitis (n/a - Recovered/Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4878** | click or scan EU-EC-10009521023 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Atrioventricular block complete (1d - Fatal - **Results in Death**) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) |
| **4879** | click or scan EU-EC-10009520936 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4880** | click or scan EU-EC-10009520928 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4881** | click or scan EU-EC-10009520818 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Male | Systemic inflammatory response syndrome (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4882** | click or scan EU-EC-10009520704 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4883** | click or scan EU-EC-10009520483 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Chills (n/a - Fatal - **Results in Death**), Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]) |
| **4884** | click or scan EU-EC-10009520360 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Cerebral infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4885** | click or scan EU-EC-10009520044 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Influenza (n/a - Not Recovered/Not Resolved - ), Pneumonitis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4886** | click or scan EU-EC-10009519982 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Gastric haemorrhage (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Portal vein thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4887** | click or scan EU-EC-10009519922 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4888** | click or scan EU-EC-10009519919 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4889** | click or scan EU-EC-10009519892 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Resuscitation (n/a - Fatal - **Results in Death**), Sudden cardiac death (n/a - Fatal - **Results in Death**), Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4890** | click or scan EU-EC-10009519867 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cerebrovascular accident (1d - Fatal - **Results in Death**, Other Medically Important Condition), Death (1d - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Intramuscular]) |
| **4891** | click or scan EU-EC-10009519866 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiac failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4892** | click or scan EU-EC-10009519846 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Nasopharyngitis (n/a - Fatal - **Results in Death**), Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4893** | click or scan EU-EC-10009519751 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4894** | click or scan EU-EC-10009519684 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4895** | click or scan EU-EC-10009519575 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pancytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4896** | click or scan EU-EC-10009519563 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4897** | click or scan EU-EC-10009519331 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4898** | click or scan EU-EC-10009519195 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Acute kidney injury (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4899** | click or scan EU-EC-10009519143 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Female | Deep vein thrombosis (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4900** | click or scan EU-EC-10009519140 | | 2021-07-28 | Healthcare Professional | Non EEA | 18-64 Years | Male | Cardiac arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pancreatic carcinoma (n/a - Fatal - **Results in Death**), Respiratory arrest (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4901** | click or scan EU-EC-10009519113 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Epilepsy (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4902** | click or scan EU-EC-10009519110 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Myocardial infarction (n/a - Fatal - **Results in Death**, Life Threatening) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4903** | click or scan EU-EC-10009518794 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Aortic stenosis (n/a - Fatal - **Results in Death**), Dyspnoea (n/a - Fatal - **Results in Death**), Platelet count decreased (n/a - Fatal - **Results in Death**), Shock (n/a - Fatal - **Results in Death**), Thrombosis (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4904** | click or scan EU-EC-10009518790 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4905** | click or scan EU-EC-10009518786 | | 2021-07-28 | Non Healthcare Professional | EEA | Not Specified | Female | COVID-19 (n/a - Not Recovered/Not Resolved - ), Circulatory collapse (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - **Results in Death**), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Peripheral vascular disorder (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4906** | click or scan EU-EC-10009518783 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4907** | click or scan EU-EC-10009518671 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**) | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4908** | click or scan EU-EC-10009518621 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**), Malaise (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4909** | click or scan EU-EC-10009518381 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Septic shock (n/a - Fatal - **Results in Death**), Urinary tract infection (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4910** | click or scan EU-EC-10009518312 | | 2021-07-28 | Non Healthcare Professional | Non EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1 {DF} - Unknown]) |
| **4911** | click or scan EU-EC-10009518262 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Malaise (2d - Fatal - **Results in Death**), Myocardial ischaemia (0d - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |
| **4912** | click or scan EU-EC-10009518243 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4913** | click or scan EU-EC-10009518114 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebrovascular accident (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4914** | click or scan EU-EC-10009518108 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Diarrhoea (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myocardial infarction (n/a - Fatal - **Results in Death**), Tachycardia (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4915** | click or scan EU-EC-10009518041 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Cardiovascular disorder (3d - Fatal - **Results in Death**), Decreased appetite (3d - Fatal - **Results in Death**), Fatigue (3d - Fatal - **Results in Death**), Fatigue (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2 {DF} - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4916** | click or scan EU-EC-10009518038 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Acute myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4917** | click or scan EU-EC-10009517977 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Myocardial infarction (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4918** | click or scan EU-EC-10009517360 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Dizziness (n/a - Fatal - **Results in Death**), Headache (n/a - Fatal - **Results in Death**), Malaise (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) |
| **4919** | click or scan EU-EC-10009516936 | | 2021-07-28 | Non Healthcare Professional | Non EEA | 18-64 Years | Female | Hyperventilation (n/a - Fatal - **Results in Death**), Malaise (1d - Fatal - **Results in Death**) | COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular]) |
| **4920** | click or scan EU-EC-10009516608 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4921** | click or scan EU-EC-10009516535 | | 2021-07-28 | Healthcare Professional | EEA | Not Specified | Male | Basilar artery thrombosis (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain injury (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Brain stem infarction (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4922** | click or scan EU-EC-10009516050 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Sudden death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4923** | click or scan EU-EC-10009516039 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Acute respiratory failure (n/a - Fatal - **Results in Death**), Hypereosinophilic syndrome (n/a - Fatal - **Results in Death**), Lung carcinoma cell type unspecified stage 0 (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4924** | click or scan EU-EC-10009516030 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Female | Pulmonary embolism (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4925** | click or scan EU-EC-10009515768 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Male | Asphyxia (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Ileus (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |

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|---|---|---|---|---|---|---|---|---|---|
| **4926** | click or scan EU-EC-10009515766 | | 2021-07-28 | Healthcare Professional | Non EEA | 18-64 Years | Female | Cardio-respiratory arrest (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4927** | click or scan EU-EC-10009515739 | | 2021-07-28 | Healthcare Professional | EEA | More than 85 Years | Not Specified | Body temperature increased (n/a - Fatal - **Results in Death**), COVID-19 (n/a - Fatal - **Results in Death**, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - **Results in Death**), Respiratory failure (n/a - Fatal - **Results in Death**), Vaccination failure (n/a - Fatal - **Results in Death**, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| **4928** | click or scan EU-EC-10009515737 | | 2021-07-28 | Healthcare Professional | Non EEA | More than 85 Years | Male | Cardiac failure acute (n/a - Fatal - **Results in Death**, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - ), Malaise (n/a - Unknown - ), Oedema peripheral (n/a - Unknown - ), Pleural effusion (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Right atrial enlargement (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - ) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) |
| **4929** | click or scan EU-EC-10009515720 | | 2021-07-28 | Healthcare Professional | Non EEA | 65-85 Years | Female | Concomitant disease progression (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| **4930** | click or scan EU-EC-10009515582 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Retroperitoneal haemorrhage (n/a - Fatal - **Results in Death**) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4931** | click or scan EU-EC-10009515573 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | COVID-19 pneumonia (n/a - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4932** | click or scan EU-EC-10009515565 | | 2021-07-28 | Non Healthcare Professional | EEA | Not Specified | Female | Death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) |
| **4933** | click or scan EU-EC-10009515496 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Female | Death (n/a - Fatal - **Results in Death**), Fatigue (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4934** | click or scan EU-EC-10009515473 | | 2021-07-28 | Non Healthcare Professional | EEA | 18-64 Years | Male | Ventricular fibrillation (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4935** | click or scan EU-EC-10009515423 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4936** | click or scan EU-EC-10009515396 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Death (n/a - Fatal - **Results in Death**) | COVID-19 VACCINE (AD26.COV2-S [RECOMBINANT]) JANSSEN [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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| # | EU Local Number | ICSR Form | EV Gateway Receipt Date | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Patient Age Group | Patient Sex | Reaction List PT(Duration - Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT- Action taken - [Duration - Dose - Route]) |
|---|---|---|---|---|---|---|---|---|---|
| **4937** | click or scan EU-EC-10009515389 | | 2021-07-28 | Non Healthcare Professional | EEA | 65-85 Years | Male | Cerebral haemorrhage (n/a - Fatal - **Results in Death**), Hypertension (n/a - Not Recovered/Not Resolved - ) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4938** | click or scan EU-EC-10009515360 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Sudden cardiac death (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4939** | click or scan EU-EC-10009515248 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Abdominal pain (n/a - Not Recovered/Not Resolved - ), General physical health deterioration (n/a - Not Recovered/Not Resolved - ), Renal failure (n/a - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4940** | click or scan EU-EC-10009515229 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Male | Extrasystoles (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - **Results in Death**), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4941** | click or scan EU-EC-10009515228 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Chronic obstructive pulmonary disease (19d - Fatal - **Results in Death**) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4942** | click or scan EU-EC-10009514835 | | 2021-07-28 | Non Healthcare Professional | EEA | More than 85 Years | Female | Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - ), Thrombosis (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) |
| **4943** | click or scan EU-EC-10009514645 | | 2021-07-28 | Healthcare Professional | EEA | 18-64 Years | Male | Cardiomyopathy (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation), Ventricular fibrillation (8d - Fatal - **Results in Death**, Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) |
| **4944** | click or scan EU-EC-10009514617 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Male | Death (n/a - Fatal - **Results in Death**, Caused/Prolonged Hospitalisation), Immunisation reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) |
| **4945** | click or scan EU-EC-10009514570 | | 2021-07-28 | Healthcare Professional | EEA | 65-85 Years | Female | Atrial fibrillation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Brain oedema (n/a - Fatal - **Results in Death**), Hemiplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Ischaemic stroke (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a - n/a - n/a]) |

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