

Line Listing Report
Time: 03/03/2023 09:50:40

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Age Group (per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form	
EU-EC-1000982480	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000983471	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000984515	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000987175	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	No	Death (n/a - Fatal - Results in Death), Underdose (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR	
EU-EC-1000987176	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	No	Death (n/a - Fatal - Results in Death), Underdose (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR	
EU-EC-1000989363	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Agitation (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Gaze palsy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	BIOPROLOL FUMARATE (C - n/a - n/a - [n/a - 10DF] - n/a), FUROSEMIDE (C - n/a - n/a - [n/a - 10DF] - n/a), LARGOPRAZOLE (C - n/a - n/a - [n/a - 10DF] - n/a), DILTIAZEM FUMARATE (C - n/a - n/a - [n/a - 10DF] - n/a), SPIRONOLACTONE (C - n/a - n/a - [n/a - 10DF] - n/a), BISOPROLOL (C - n/a - n/a - [n/a - 10DF] - n/a), BISOPROLOL POTASSIUM (C - n/a - n/a - [n/a - 10DF] - n/a)	ICSR	
EU-EC-1000989625	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Acute disseminated encephalomyelitis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Acute myocardial infarction (n/a - Unknown - Life Threatening, Other Medically Important Condition), Aphasia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Blood pressure increased (n/a - Unknown - Life Threatening, Other Medically Important Condition), Brain death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Brain oedema (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cerebral haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Life Threatening, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Corns (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Demyelination (n/a - Unknown - Life Threatening, Other Medically Important Condition), Haemiparesis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypertensive crisis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Life Threatening, Other Medically Important Condition), Pyramidal tract syndrome (n/a - Unknown - Life Threatening, Other Medically Important Condition), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition), Thrombosis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Tinnitus increased (n/a - Unknown - Life Threatening, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10DF] - Intramuscular)	Not reported	ICSR	
EU-EC-10009897385	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Aortic thrombosis (1d - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myoplegia (2d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10DF] - Intramuscular)	ACETYLSALICYLIC ACID (C - n/a - n/a - [n/a - n/a]), BUDESONIDE (C - n/a - n/a - [n/a - n/a]), SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE, SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE (C - n/a - n/a - [n/a - n/a]), SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE (C - n/a - n/a - [n/a - n/a])	ICSR	
EU-EC-10009897675	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10009898303	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	COVID-19 (n/a - Fatal - Results in Death), COVID-19 pneumonia (n/a - Fatal - Results in Death), Cachexia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dementia (n/a - Fatal - Results in Death), Urinary tract infection (n/a - Fatal - Results in Death), Vaccination failure (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009891057	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Adult	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-100098971086	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009897265	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death), Hepatic function abnormal (n/a - Unknown -), Neutropenia (n/a - Unknown -), Portal vein thrombosis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), FULVESTRANT (FULVESTRANT) (S - Hormone receptor positive breast cancer - Unknown - [n/a - n/a - n/a]), IBRANCE (PALBOICICLIS) (S - Hormone receptor positive breast cancer - Unknown - [n/a - n/a - Oral])	Not reported	ICSR	
EU-EC-10009897265	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) (TOZINAMERAN) (S - COVID-19 - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009897268	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	FENTANYL, FENTANYL CITRATE (C - n/a - n/a -), PANTOPRAZOLE, PANTOPRAZOLE SODIUM BESILATE (C - n/a - n/a -), ACETYLSALICYLIC ACID (C - n/a - n/a -), CALCIUM CITRATE, MACE STARCH, STEARIC ACID, Talc, CALCIUM CITRATE (C - n/a - n/a -), COLECALCIFEROL (C - n/a - n/a -), ENOXAPARIN SODIUM (C - n/a - n/a -), FOLIC ACID, DRIED FERROUS SULFATE (C - n/a - n/a -), FUROSEMIDE (C - n/a - n/a -), IBROSUASTATIN CALCIUM (C - n/a - n/a -), SPIRONOLACTONE (C - n/a - n/a -)	ICSR	
EU-EC-10009897321	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [2d - 10DF] - Intramuscular)	Not reported	ICSR	
EU-EC-10009895157	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Arrhythmia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -), Inappropriate schedule of product administration (n/a - Unknown -), Palpitations (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ASCORBIC ACID (C - n/a - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10009895160	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	MEFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Type 2 diabetes mellitus - n/a - [n/a - 500mg - n/a])	ICSR	
EU-EC-10009898720	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	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), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	TAMBU (GSELTAMIBUR, GSELTAMIBUR PHOSPHATE) (C - n/a - n/a - [n/a - n/a - n/a]), BETAMETHASONE, BETAMETHASONE SODIUM PHOSPHATE (C - n/a - n/a - [n/a - 6mg - Intramuscular]), [CHLORPHENIRAMINE MALEATE, LACTOSE] (C - n/a - n/a - [n/a - n/a - n/a]), DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE (C - n/a - n/a - [n/a - 200mg - n/a]), ENOXAPARIN SODIUM (C - n/a - n/a - [n/a - 40mg - Subcutaneous]), SIMVASTATIN (C - n/a - n/a - [n/a - 10mg - n/a])	ICSR	
EU-EC-10009895652	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 10DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), PERTUZUMAB (PERTUZUMAB) (S - n/a - Not applicable - [n/a - n/a - n/a]), TRASTUZUMAB (TRASTUZUMAB) (S - n/a - Not applicable - [n/a - n/a - n/a])	CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM) (C - n/a - n/a - [n/a - n/a - n/a]), CALCIUM PHOSPHATE (C - n/a - n/a - [n/a - n/a - n/a]), ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009894031	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Male	No	No	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009894856	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE (C - Anal tablet - n/a - [n/a - n/a - n/a]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009895657	31/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-100098940178	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	85-95 Years	Not Specified	Male	No	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10009894365	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Breast pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009894376	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death, Other Medically Important Condition), Miasma (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 3mL - n/a])	Not reported	ICSR	
EU-EC-10009894372	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Conjunctivitis (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Rash (n/a - Unknown -), Skin lesion (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10009894370	31/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Blood glucose abnormal (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown -), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009894482	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Back pain (n/a - Unknown -), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10009895051	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Male	No	No	Brucellosis/sepsis (n/a - Recovering/Resolving -), Cardiac flutter (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Septic shock (13d - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10DF] - Intramuscular)	Not reported	ICSR	
EU-EC-10009894555	31/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009894245	30/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Confusion (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), Erythema (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), 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 - 10DF] - Intramuscular), COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 10DF] - n/a)	BRIVACT FILM COATED TABLETS 75 MG (BRIVARACETAM) (C - Epilepsy - n/a - [n/a - n/a - Oral]), EPOETIN ALFA HEXAL 40,000 IU/1 ML SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE (EPOETIN ALFA) (C - Anaemia - n/a - [n/a - n/a - n/a]), FILGRASTIM HEXAL 48 MU/0.5 ML SOLUTION FOR INJECTION OR INFUSION IN PRE-FILLED SYRINGE (FILGRASTIM) (C - Anaemia - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - Gastroesophageal reflux prophylaxis - n/a - [n/a - n/a - Oral]), [DEXAMETHASONE] (C - Lung neoplasm malignant, Metastases to central nervous system - n/a - [n/a - n/a - Oral]), [PHENTONIN SODIUM] (C - Epilepsy - n/a - [n/a - n/a - Oral]), SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROIC ACID, SODIUM VALPROATE (C - Epilepsy - n/a - [n/a - n/a - Oral])	ICSR	
EU-EC-10009897718	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Arrhythmia (n/a - Fatal - Results in Death), Cardiac discomfort (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Peripheral vascular disorder (n/a - Fatal - Results in Death), Skin ulcer (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10009892483	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009892854	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	No	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])	Not reported	ICSR	
EU-EC-10009892856	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death), Miasma (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009892857	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009892812	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Adult	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009893505	30/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009893643	30/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Chest pain (n/a - Fatal - Results in Death), Death (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])	Not reported	ICSR	
EU-EC-10009893660	30/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Common artery disease (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])	Not reported	ICSR	
EU-EC-10009893226	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	ICSR	
EU-EC-10009893252	30/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Pyrexia (n/a				

EU Local Number	EY Category	Report Type	Primary Cause	Primary Country	Literature Reference	Age Group (at report)	Sex	Patent Status	Patent No.	Parent Drug	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100093454	3/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Female	Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Disease recurrence (n/a - Unknown -), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urinary tract infection (n/a - Unknown -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[GALANTAMINE] (C - Dementia - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100093500	3/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Female	Aspirin (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Fall (n/a - Unknown -), Malaise (n/a - Unknown -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - 75mg - n/a]), [ATORVASTATIN] (C - Blood cholesterol increased - n/a - [n/a - 20mg - n/a]), [BETAMETHASONE] (C - Glaucoma - n/a - [n/a - 20mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 1.25mg - n/a]), [METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 400mg - n/a]), [MOPRAZOLE] (C - n/a - n/a - [n/a - 50mg - n/a]), [PARAFFIN, LIGHT LIQUID, PARAFFIN LIGHT LIQUID, PARAFFIN WHITE SOFT] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100093584	3/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Female	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved -), Hypotension (n/a - Not Recovered/Not Resolved -), Central haemorrhage (n/a - Fatal - Results in Death), Corns (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NARSIFIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100093139	28/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[NARSIFIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100090318	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	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)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-100091154	27/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Male	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Vaccination site pain (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100091877	27/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Female	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091297	27/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100091491	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100091542	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100091614	27/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Male	Cardiac death (n/a - Fatal - Results in Death), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100091576	27/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100091704	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091782	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Female	Acute megakaryocytic leukaemia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown -), Confusion (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100093669	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Male	Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000979750	26/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Male	Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Blood pressure abnormal - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000979772	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Male	Death (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100090751	26/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diet refusal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Emotional distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Failure to thrive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-100090056	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Male	Death (n/a - Fatal - Results in Death), Pulmonary thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100091010	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CLINDIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREGIBLASTAT] (C - n/a - n/a - [n/a - n/a - n/a]), [TRILAGLIFITIN SUCCLINATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100091911	26/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100090410	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Male	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100090433	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Male	Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Downing (n/a - Fatal - Results in Death), Physical deconditioning (n/a - Unknown -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100090451	26/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Male	Asthma (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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100090476	26/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Female	Death (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100090481	26/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Male	Blood pressure increased (n/a - Unknown -), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Oxygen saturation decreased (n/a - Unknown -), Pain (n/a - Not Recovered/Not Resolved -), Thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100097047	25/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Male	Cardiac arrest (6d - Fatal - Results in Death), Death (6d - Fatal - Results in Death), Oxidative peripheral (6d - Fatal - Results in Death), Pulmonary embolism (6d - Fatal - Results in Death), Respiratory failure (6d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10mg - Intramuscular])	[KEPPRA 750 MG FILM-COATED TABLETS (LEVETIRACETAM)] (C - Epilepsy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100097030	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Female	Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Asthma (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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100097037	25/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100097472	25/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Male	Death (3d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10mg - n/a])	[FLUVOXAMINE MALEATE] (C - Antidepressant therapy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100097645	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Male	Chest pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Extra dose administered (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000976139	25/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100097624	25/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Female	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000975762	25/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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 (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100097864	25/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000976123	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000978276	24/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - 2.5mg - 10mg]), [FENELGLIPTIN HYDROBROMIDE HYDRATE, CANAGLIFLOZIN] (C - Diabetes mellitus - n/a - [n/a - 1mg - 10mg])	ICSR
EU-EC-1000978281	24/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000978331	24/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Female	Cardiovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000975020	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Male	Death (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10mg - Intramuscular])	Not reported	ICSR
EU-EC-1000975923	24/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Female	Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eye movement disorder (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Organ failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BAGLOFEN] (C - n/a - n/a - [n/a - 20mg - n/a]), [CITIDINE] (C - n/a - n/a - [n/a - 400mg - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 400mg - n/a])	ICSR
EU-EC-1000975281	24/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Male	Secure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), 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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ELIQUIS (APIXIBAN)] (C - n/a - n/a - [n/a - n/a - n/a]), [SAMSCA (TICAGLIFITIN)] (C - n/a - n/a - [n/a - n/a - n/a]), [TELMISARTAN (TELMISARTAN)] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOZAZOL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOROMETHOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TULOBUTEROL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000978096	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Male	No	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000978218	24/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	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)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000978274	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	

EU Local Number	EY Category Review Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chir - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chir - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
EU-EC-100076046	23/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	Not Specified	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), Congenital anomaly (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) Death neonatal (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000761028	23/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Neonate (Premature and Term newborns)	Not Specified	Not Specified	Death neonatal (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL (C - n/a - n/a - [n/a - n/a - n/a]), RABEPRAZOLE, RABEPRAZOLE SODIUM (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-100074281	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Asthma (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])	Not reported	ICSR	
EU-EC-1000743215	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Male	Not Specified	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])	Not reported	ICSR	
EU-EC-1000743414	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Male	Not Specified	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 -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000745912	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Female	Not Specified	Toxic shock syndrome (n/a - Unknown - Other Medically Important Condition) 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])	[ALLOPURINOL] (C - n/a - n/a - [n/a - 300mg - n/a]), [ENALAPRIL MALEATE, ENALAPRILAT] (C - n/a - n/a - [n/a - 20mg - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 12.5mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1000mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - n/a]), [SMVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - n/a]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 10mg - n/a])	ICSR	
EU-EC-1000745913	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	Not Specified	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])	Not reported	ICSR	
EU-EC-1000745976	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Male	Not Specified	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000746028	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	Not Specified	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), Fibrile convulsion (n/a - Unknown -), Pyrexia (n/a - Unknown -), Sepsis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000746561	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	Not Specified	Toxic shock syndrome (n/a - Unknown - Other Medically Important Condition) Asthma (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])	Not reported	ICSR	
EU-EC-1000748234	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Male	Not Specified	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])	Not reported	ICSR	
EU-EC-1000722523	19/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Female	Not Specified	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000730013	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	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), Mucositis (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])	[SIMPON (SOLIMUMAM)] (C - n/a - Unknown - [n/a - 50mg - n/a]), [FOLIC ACID] (C - n/a - n/a -), [MELGICAM] (C - n/a - Unknown - [n/a - 15mg - n/a]), [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SEQUIHYDRATE] (C - n/a - Unknown - [1DF - n/a])	ICSR	
EU-EC-1000730047	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Male	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(DF) - Intramuscular])	Not reported	ICSR	
EU-EC-1000730705	19/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Male	Not Specified	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disability), Muscle tightness (n/a - Unknown - Other Medically Important Condition), Neuropathic pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disability), Swelling (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ATORVASTATIN] (C - n/a - n/a - [n/a - 10mg - n/a]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 120mg - n/a]), [GLIMEPIRIDE] (C - n/a - n/a - [n/a - 4mg - n/a]), [ISOSORBIDE] (C - n/a - n/a - [n/a - 60mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 125ug - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 160mg - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - 2.5mg - n/a])	ICSR	
EU-EC-1000734322	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	Not Specified	Anemia (n/a - Unknown -), Anisofibrinogen (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), Haemoglobin 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), Orthopnea (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])	[WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MELGICAM] (C - n/a - n/a - [n/a - n/a - n/a]), [SMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000734505	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	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])	Not reported	ICSR	
EU-EC-1000734844	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	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 - [2(DF) - 1(DF) - Intramuscular])	Not reported	ICSR	
EU-EC-1000738765	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - n/a])	CYMBALTA (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Depression - n/a - [n/a - 60mg - Oral]), [IBUPROFEN, IBUPROFEN, IBUPROFEN SODIUM] (C - Headache - n/a - [n/a - n/a - n/a]), [PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Thrombosis prophylaxis - n/a - [n/a - 75mg - Oral]), [ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE] (C - Osteoporosis - n/a - [n/a - 70mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hypercholesterolaemia - n/a - [n/a - 40mg - Oral]), [CODIENE PHOSPHATE SEQUIHYDRATE] (C - Headache - n/a - [n/a - 25mg - Oral]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - Oral]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - Iron deficiency - n/a - [n/a - 100mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 1000mg - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE, QUETIAPINE HEMIFUMARATE] (C - Depression - n/a - [n/a - 100mg - Oral]), [TERBUHALIN SULFATE] (C - Bronchospasm - n/a - [n/a - 5mg - Respiratory (inhalation)])	Not reported	ICSR
EU-EC-1000739013	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	Death (S) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000731531	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Female	Not Specified	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])	Not reported	ICSR	
EU-EC-1000716896	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Neonate (Premature and Term newborns)	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])	Not reported	ICSR	
EU-EC-1000717804	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Female	Not Specified	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])	Not reported	ICSR	
EU-EC-1000717806	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	Acute ischaemia (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])	Not reported	ICSR	
EU-EC-1000718705	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	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])	Not reported	ICSR	
EU-EC-1000720601	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Male	Not Specified	Cerebrovascular disorder (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000728006	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	Acute leukaemia (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])	Not reported	ICSR	
EU-EC-1000722280	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000734563	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Male	Not Specified	Aphasia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), C-reactive protein increased (n/a - Unknown -), Coordination abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Dysarthria (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Encephalitis viral (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Epilepsy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Meningoencephalitis viral (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[APRYMBAN (APRYMBAN)] (C - Endothem, Pseudomonas - n/a - [n/a - n/a - n/a]), [BMATORPROST (BMATORPROST)] (C - Glaucoma - n/a - [n/a - n/a - n/a]), [LEVETIRACETAM (LEVETIRACETAM)] (C - Epilepsy - n/a - [n/a - n/a - n/a]), [BENNA (BENNOXIDE A+B) (BENNOXIDE A+B)] (C - Constipation - n/a - [n/a - n/a - n/a]), [ACICLOVIR, ACICLOVIR SODIUM] (C - Encephalitis - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - Gout - n/a - [n/a - n/a - n/a]), [AMOXICILLIN, POTASSIUM CLAVULANATE] (C - Angioma - n/a - [n/a - n/a - n/a]), [CEFTRIAXONE, CEFTRIAXONE SODIUM] (C - Encephalitis - n/a - [n/a - n/a - n/a]), [BORZOLAMIDE HYDROCHLORIDE, TIMOLOL, BORZOLAMIDE HYDROCHLORIDE, TIMOLOL MALEATE, BORZOLAMIDE, TIMOLOL] (C - Glaucoma - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - Abdominal pain upper, Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a])	ICSR	

EU Local Number	EY Category	Report Date	Report Type	Primary Source	Primary Source Country	Literature Reference	Patent Age Group	Patent Status	Patent Sex	Patent Age Group	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chn - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chn - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
											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 -)		[LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - n/a - n/a]), [MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE, MORPHINE SULPHATE BPF] (C - Pain - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Pain - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [SODIUM HYALURONATE] (C - Glaucoma - n/a - [n/a - n/a - n/a])	
EU-EC-1000732842	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000701831	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Not Specified	Female	No	Arrhythmia (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])	Not reported	ICSR
EU-EC-1000702848	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000702896	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	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])	Not reported	ICSR
EU-EC-1000705093	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death) 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 - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000706378	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000706383	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000707610	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000707747	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000707790	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	Cardiac disorder (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000707799	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Elderly	Male	No	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])	Not reported	ICSR
EU-EC-1000691550	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death) Myocardial infarction (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000698304	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000698360	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000698587	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Male	No	Cardio-respiratory arrest (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000698683	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Not Specified	Male	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Life Threatening), Pneumonia (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000694296	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Male	No	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])	[CALCITRIOL] (C - n/a - n/a - [n/a - 500 - n/a]), [CANRENONE, POTASSIUM CANRENONE] (C - n/a - n/a - [n/a - 50mg - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 150mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a])	ICSR
EU-EC-1000696014	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Not Specified	Male	No	Asthma (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), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000696980	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	Death (2d - Fatal - Results in Death) Central 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])	[JANUVIA [STAGLIPTIN, STAGLIPTIN PHOSPHATE, STAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LANTUS [INSULIN GLARGINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-1000697441	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1(D)F - n/a])	Not reported	ICSR
EU-EC-1000696796	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Female	No	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), Dyspnoea (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 (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000695473	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Male	No	Cerebrovascular accident (1d - Unknown/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])	[DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DUTASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [BIMAZAPRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BIPHENAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPRIMOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [METOPROLOL TARTRATE, METOPROLOL TARTRATE BPF] (C - n/a - Unknown - [n/a - n/a - n/a]), [MOLSDOMINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [SMVASTATIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [TICLOPIDINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-1000698193	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Male	No	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])	[METOPROLOL TARTRATE, METOPROLOL TARTRATE BPF] (C - n/a - Unknown - [n/a - n/a - n/a]), [MOLSDOMINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [SMVASTATIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [TICLOPIDINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-1000697577	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Female	No	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])	Not reported	ICSR
EU-EC-1000696812	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Male	No	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000696070	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Not Specified	Female	No	Respiratory failure (21d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000696196	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000696182	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Female	No	Pulmonary embolism (n/a - Fatal - Results in Death) 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), 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])	Not reported	ICSR
EU-EC-1000696454	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Fibrin D dimer increased (1d - Fatal - Results in Death), Leucocytosis (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])	[BROMAZEPAM] (C - n/a - Unknown - [n/a - n/a - n/a]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM)] (C - n/a - Unknown - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-1000696410	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000696493	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000696487	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Elderly	Male	No	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])	Not reported	ICSR
EU-EC-1000696823	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000696816	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000694913	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Urine output decreased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000695198	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000695203	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (3d - Fatal - Results in Death), Death (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000695322	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Male	No	Chills (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)F - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [NIFEDIPINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000695877	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death) Cardiac arrest (3d - Fatal - Results in Death), Death (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYL SALICYLIC ACID] (C - n/a - Unknown -), [NEBIVOLOL] (C - n/a - Unknown -), [OLMESARTAN MEDOXOMIL, OLMESARTAN] (C - n/a - Unknown -), [SMVASTATIN] (C - n/a - Unknown -)	ICSR
EU-EC-1000695817	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2(D)F - n/a])	Not reported	ICSR
EU-EC-1000693841	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Male	No	Death (3d - 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(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000693468	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Not Specified	Female	No	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])	Not reported	ICSR
EU-EC-1000694042	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	15-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2(D)F - n/a])	Not reported	ICSR
EU-EC-1000694370	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not available	More than 65 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000695285	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Bradypnoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000695262	08/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death),<			

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Purpose	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
												<p>LERCANDIPINE HYDROCHLORIDE (C - n/a - Unknown - [n/a - 20mg - n/a]),</p> <p>MICRONISED PURIFIED FLAVONOID FRACTION (C - n/a - Unknown - [n/a - 500mg - n/a]),</p> <p>PYRIDOXINE HYDROCHLORIDE, VITAMIN B6 (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>IRIMENDINE (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(SILYBUM MARIANUM) (C - n/a - Unknown - [n/a - n/a - n/a]),</p>	
EU-EC-1000927631	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hypotension (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])		ICSR
EU-EC-100092648	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	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])	Not reported	ICSR
EU-EC-1000928171	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	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), Hypertension (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), Sensory 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])	Not reported	ICSR
EU-EC-100092625	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100092631	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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])	Not reported	ICSR
EU-EC-1000921261	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	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])	Not reported	ICSR
EU-EC-1000931722	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [2d - 2dF] - Intramuscular)	DARATUMUMAB (DARATUMUMAB) (C - n/a - n/a -), IBLUTINS (IBLUTINS) (C - n/a - n/a -)	ICSR
EU-EC-1000931848	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1dF] - Intradermal)	Not reported	ICSR
EU-EC-100093330	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Pain in extremity (n/a - Not Recovered/Not Resolved -), Vaccination site haemorrhage (n/a - Not Recovered/Not Resolved -), Vaccination site nodules (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])	Not reported	ICSR
EU-EC-1000918495	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000911916	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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])	<p>LIXIANA (EDOXABAN, EDOXABAN TOBYLATE) (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY MAGNESIUM (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(BISPHENOL, BISPHENOL, DIMETHACRYLATE, BISPHENOL, HEMIFUMARATE) (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(CALCIUM CITRATE) (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(COLICALDIFEROL) (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(DIGNIN, DIGNIN PH, EUR) (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(DIONEPEZIL) (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(HALOPERIDOL, HALOPERIDOL DECANOATE) (C - n/a - Unknown - [n/a - n/a - n/a]),</p> <p>(QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - Unknown - [n/a - n/a - n/a])</p>	ICSR
EU-EC-1000912402	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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])	Not reported	ICSR
EU-EC-1000912439	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 2dF] - n/a)	Not reported	ICSR
EU-EC-1000915995	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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 - 1dF] - Intramuscular)	Not reported	ICSR
EU-EC-1000916073	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1dF] - Intramuscular)	METFORMIN, METFORMIN HYDROCHLORIDE (C - n/a - n/a -)	ICSR
EU-EC-1000916528	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Fatal - Results in Death), Chills (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Feeling cold (n/a - Fatal - Results in Death), Gastrointestinal haemorrhage (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Skin discoloration (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000918732	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hepes 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])	Not reported	ICSR
EU-EC-1000920158	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Apnoea respiration (n/a - Unknown - Other Medically Important Condition), Asthma (n/a - Unknown -), COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -), Hypoxia (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000959590	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1dF] - Intramuscular)	Not reported	ICSR
EU-EC-1000959759	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Corns (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])	Not reported	ICSR
EU-EC-1000959847	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	(BUPRENORPHINE, MELOXICAM) (C - Rheumatoid arthritis - n/a - [n/a - 15mg - Oral]), (METHOTREXATE) (C - Rheumatoid arthritis - n/a - [n/a - 2.5mg - Oral]), (METHYLPREDNISOLONE) (C - Rheumatoid arthritis - n/a - [n/a - 4mg - Oral])	ICSR
EU-EC-1000959853	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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])	(ACICLOVIR) (C - Anal fistula - Unknown - [n/a - n/a - n/a]), (CARVEDILOL) (C - n/a - Unknown - [n/a - n/a - n/a]), (LOSARTAN, LOSARTAN POTASSIUM) (C - n/a - Unknown - [n/a - n/a - n/a]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-1000959839	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Coagulopathy (5d - Fatal - Results in Death), Death (5d - Fatal - Results in Death), Haemorrhagic transformation (5d - Fatal - Results in Death), Hemiplegia (5d - Fatal - Results in Death), Ischaemic stroke (5d - Fatal - Results in Death), Name 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])	(ANHYDROUS LEVOTHYROXINE SODIUM) (C - n/a - Unknown - [n/a - 1dF] - n/a), (CLONAZEPAM) (C - n/a - Unknown - [n/a - 1dF] - n/a), (COLICALDIFEROL, CALCIUM, COLICALDIFEROL, CALCIUM CARBONATE) (C - n/a - Unknown - [n/a - 1dF] - n/a), (DIOXOLAMINE) (C - n/a - Unknown - [n/a - 2dF] - n/a), (DOPPELBEI) (C - n/a - Unknown - [n/a - 3dF] - n/a), (FENOFIBRATE, FENOFIBRATE MALATE) (C - n/a - Unknown - [n/a - 1dF] - n/a), (FENOFIBRATE, FENOFIBRATE (NANONISEN)) (C - n/a - Unknown - [n/a - 1dF] - n/a), (GABAPENTIN) (C - n/a - Unknown - [n/a - 1dF] - n/a), (LERCANDIPINE HYDROCHLORIDE) (C - n/a - Unknown - [n/a - 1dF] - n/a), (MICRONISED SPIRONOLACTONE, SPIRONOLACTONE) (C - n/a - Unknown - [n/a - 1dF] - n/a), (PANTOPRAZOLE) (C - n/a - Unknown - [n/a - 1dF] - n/a), (SODIUM ASCORBATE, FERROUS SULFATE) (C - n/a - Unknown - [n/a - 1dF] - n/a), (TRAMADOL HYDROCHLORIDE) (C - n/a - Unknown - [n/a - 2dF] - n/a), (ZINC) (C - n/a - Unknown - [n/a - n/a - n/a]), (DOLIPIDEM TARTRATE) (C - n/a - Unknown - [n/a - 1dF] - n/a)	ICSR
EU-EC-1000959883	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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])	Not reported	ICSR
EU-EC-1000959556	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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])	Not reported	ICSR
EU-EC-1000959616	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	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])	Not reported	ICSR
EU-EC-1000960918	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Hepes zoster (n/a - Recovered/Resolved With Sequela - Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Recovered/Resolved With Sequela - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Recovered/Resolved With Sequela - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Recovered/Resolved With Sequela - Caused/Prolonged Hospitalisation), Throat tightness (n/a - Recovered/Resolved With Sequela - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000960195	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	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])	Not reported	ICSR
EU-EC-1000960182	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthma (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])	Not reported	ICSR
EU-EC-1000960495	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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])	Not reported	ICSR

EU Local Number	EY Category	Report Type	Primary Source	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Age Group (as per report)	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100056080	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100056510	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100056866	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	Death (S) - Fatal - Results in Death, Caused/Prolonged Hospitalisation	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100056870	04/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	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])	Not reported	ICSR
EU-EC-100056770	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100056916	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ATENOLOL, ATENOLOL, EP] (C - n/a - n/a -), [CLOZAPINE] (C - n/a - n/a -), [DUFATERIDE] (C - n/a - n/a -), [FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL, XINOPATE] (C - n/a - n/a -), [POFOMYCIN] (C - n/a - n/a -), [PARACETAMOL, PARACETAMOL, CODINE PHOSPHATE HEMHYDRATE] (C - n/a - n/a -), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a -), [BERTRALINE HYDROCHLORIDE] (C - n/a - n/a -), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a -), [VALPROATE SEMISODIUM] (C - n/a - n/a -)	ICSR
EU-EC-100056215	04/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Agueusia (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])	Not reported	ICSR
EU-EC-100056750	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	Not Specified	Death (n/a - Fatal - Results in Death), Feeding disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100056716	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	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])	Not reported	ICSR
EU-EC-100056702	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	No	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])	Not reported	ICSR
EU-EC-100056740	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-100056706	03/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	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])	Not reported	ICSR
EU-EC-100056724	03/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, FLUMARATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100056714	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	No	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])	Not reported	ICSR
EU-EC-100056772	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-100056847	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	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])	Not reported	ICSR
EU-EC-100056054	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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 enocytosis (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])	Not reported	ICSR
EU-EC-100056153	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[D] - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ROZUVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETHASONE DIPROPIONATE, FORMOTEROL, FLUMARATE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL, FLUMARATE DIHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100056231	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	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])	[LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE] (C - Diarrhoea - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Reflux gastritis - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100056264	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	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])	RIVASTIGMINE (RIVASTIGMINE, RIVASTIGMINE HYDROGEN TARTRATE) (C - Parkinson's disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100056473	02/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	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])	[ACETYSALICYLIC ACID] (C - Central infection - n/a - [n/a - n/a - Oral]), [BACILLUS SUBTILIS, LACTOAMIN, BIFIDOBACTERIUM] (C - Constipation - n/a - [n/a - n/a - Oral]), [CASSIA SENNA GLYCOSIDES STANDARDIZED 60%, SENNOSIDES CALCIUM SALTS] (C - Constipation - n/a - [n/a - n/a - Oral]), [DANKENJUTO, GINGER, GINSENG, ZANTHOXYLUM FRUIT, GINSENG] (C - Anal stenosis - n/a - [n/a - n/a - Oral]), [DIMETHYL POLYSILOXANE (SILICONE ANTIFOAM AF30), DIMETICONE] (C - Constipation - n/a - [n/a - n/a - Oral]), [MAGNESIUM OXIDE] (C - Constipation - n/a - [n/a - n/a - Oral]), [MOSAPRIDE, MOSAPRIDE CITRATE] (C - Anal stenosis - n/a - [n/a - n/a - Oral]), [PHENOBARBITAL] (C - Epilepsy - n/a - [n/a - n/a - Oral]), [RABEPRAZOLE, RABEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-100056098	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	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])	Not reported	ICSR
EU-EC-100056125	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	No	Anaemia (n/a - Unknown -), Atrial fibrillation (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])	[SAMSCA (TOLVAPTAN)] (C - Cardiac failure - n/a - [n/a - 7.5mg - Oral]), [SGLX03N (SGLX03N)] (C - Energy metabolic hyperkalaemia - n/a - [n/a - 4mg - Oral]), [XARELTO (RIVAROXABAN)] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral]), [CANVEDOLOL] (C - Atrial fibrillation - n/a - [n/a - 2.5mg - Oral]), [FUROSEMIDE] (C - Cardiac failure - n/a - [n/a - 20mg - Oral]), [LANOSAPROLOL] (C - Angina pectoris - n/a - [n/a - n/a - Oral]), [RIVASTIGMINE] (C - Dementia - n/a - [n/a - 4.5mg - Topical]), [SPIRONOLACTONE] (C - Cardiac failure - n/a - [n/a - 25mg - Oral])	ICSR
EU-EC-100056194	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death), Incontinence (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100056470	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 2[D] - n/a])	Not reported	ICSR
EU-EC-100056457	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 2[D] - n/a])	Not reported	ICSR
EU-EC-100056474	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1[D] - Intramuscular])	Not reported	ICSR
EU-EC-100056475	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1[D] - Intramuscular])	Not reported	ICSR
EU-EC-100056426	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	No	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), Pleurisy effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[XARELTO (RIVAROXABAN)] (C - Anal fibrillation - n/a - [n/a - 20mg - Oral]), [ATENOLOL, ATENOLOL, EP] (C - Atrial fibrillation - n/a - [n/a - 50mg - Oral]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-100056260	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	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 -), Neutrophilic (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100056281	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	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])	Not reported	ICSR
EU-EC-100056266	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Female	Not Specified	No	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), Cardiovascular 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), Hriness (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])	Not reported	ICSR
EU-EC-100056363	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Adrenalitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cheril 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[D] - Intramuscular])	Not reported	ICSR
EU-EC-100056340	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100056347	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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])	Not reported	ICSR
EU-EC-100056407	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100056416	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	No	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])	Not reported	ICSR
EU-EC-100056397	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	HYDROCORTISONE, HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Purpose	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
											(CLEMASTINE, CLEMASTINE FUMARATE) (C - n/a - n/a - [n/a - 1mg - n/a]), (DIAZEPAM) (C - n/a - n/a - [n/a - 5mg - n/a]), (ECONAZOLE NITRATE) (C - n/a - n/a - [n/a - n/a]), (ESOMEPRAZOLE MAGNESIUM DIHYDRATE) (C - n/a - n/a - [n/a - 20mg - n/a]), (GABAPENTIN) (C - n/a - n/a - [n/a - 300mg - n/a]), (LACTULOSE, LACTULOSE, LIQUID) (C - n/a - n/a - [n/a - 20ml - n/a]), (MOMETASONE FURIOATE, MOMETASONE FURIOATE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a]), (MORPHINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 30mg - n/a]), (OXYCODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 10mg - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - 1000mg - n/a]), (PROPRIMAZINE, PROPRIMAZINE MALEATE) (C - n/a - n/a - [n/a - 50mg - n/a]), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - n/a - n/a]), (ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 125mg - n/a])	ICSR
EU-EC-1000593646	23/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	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), Confusion (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)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
EU-EC-10005904146	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
EU-EC-1000591167	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	ADAMTS13 activity decreased (n/a - Fatal - Results in Death), Autoimmune disorder (n/a - Fatal - Results in Death), Coagulopathy (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pericardial tamponade (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death), Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death)	BIKARVY (EMTRICITABINE, TENOFOVIR ALAFANEMIDE, BICTEGRAVIR) (S - n/a - Unknown - [n/a - 1DF] - n/a), COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), (FLUCONAZOLE) (S - n/a - Unknown - [n/a - 1DF] - n/a), (SULFAMETHOXAZOLE, TRIMETHOPRIM) (S - n/a - Unknown - [n/a - 5DF] - n/a)	Not reported	ICSR
EU-EC-1000591308	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591318	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591321	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591420	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death), Toxicity (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591487	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Immune reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591523	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Male	Asthma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591546	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591560	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Elderly	Female	Fatigue (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591576	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000591821	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591876	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Elderly	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 (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591870	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591953	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591964	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000591919	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - 2DF] - n/a)	Not reported	ICSR
EU-EC-1000592043	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Chills (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - 3ml - intramuscular])	Not reported	ICSR
EU-EC-1000592107	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Pneumonitis (n/a - Recovered/Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000592115	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000592120	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000592167	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000592296	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000592273	28/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(GLICLAZIDE) (C - Diabetes mellitus - n/a - [n/a - 120mg - n/a]), (METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP) (C - Diabetes mellitus - n/a - [n/a - 3000mg - n/a])	ICSR
EU-EC-1000592364	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000592392	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	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 (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000592340	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000592340	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	Brain injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - 2DF] - n/a)	Not reported	ICSR
EU-EC-1000592366	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000592377	28/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-1000592426	28/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000592818	27/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	Acute kidney injury (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	XARELTO (RIVAROXABAN) (C - n/a - n/a -)	ICSR
EU-EC-1000493412	27/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Ibuprofen (n/a - Unknown - Caused/Prolonged Hospitalisation), Immobilisation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(AMLODIPINE) (C - n/a - n/a - [n/a - n/a - n/a]), (ENALAPRIL, ENALAPRIL MALEATE) (C - n/a - n/a - [n/a - n/a - n/a]), (HYDROXYMETHOXYAZOLE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000496284	27/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Acute kidney injury (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Hepatic failure (n/a - Fatal - Results in Death), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pancreatitis chronic (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	CIRCADIN (MELATONIN) (C - n/a - n/a - [n/a - n/a - Oral]), (AMYLASE, LIPASE, PROTEASE, PANCREALIPASE, PANCREAS POWDER, PANCREATIN) (C - n/a - n/a - [n/a - 1DF] - Oral), (CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE) (C - n/a - n/a - [n/a - 10mg - Oral]), (CYANOCOBALAM, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 10DF] - Oral), (DICLOFENAC, DICLOFENAC DIETHYLAMINE, DICLOFENAC EPOLAMINE, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM, DICLOFENAC SODIUM PH. EUR.) (C - n/a - n/a - [n/a - 50mg - Oral]), (PARACETAMOL) (C - n/a - n/a - [n/a - 1g - n/a])	ICSR
EU-EC-1000496201	26/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Life Threatening), Dyspnoea (1d - Fatal - Results in Death, Life Threatening), Dyspnoea (2d - Fatal - Results in Death, Life Threatening), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000496375	26/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fluid retention (n/a - Unknown -), Liver disorder (n/a - Unknown -), Pyrexia (n/a - Unknown -), Malaise (n/a - Unknown - Other Medically Important Condition), Thrombotic (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000497227	26/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000497238	26/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Aphasia (n/a - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (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), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Gait inability (n/a - Fatal - Results in Death, Other Medically Important Condition), Hemiparesis (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypoglycaemia (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death, Other Medically Important Condition), Tachycardia (n/a - Fatal - Results in Death, Other Medically Important Condition), Thrombocytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(ASCORBIC ACID) (C - n/a - n/a - [n/a - 100mg - Oral]), (ENOXAPARIN SODIUM) (C - n/a - n/a - [n/a - 40mg - Subcutaneous]), (PARACETAMOL) (C - n/a - n/a - [n/a - 1500mg - Oral]), (PREDNISONE) (C - n/a - n/a - [n/a - 15mg - Oral]), (ZINC) (C - n/a - n/a - [n/a - 20mg - Oral])	ICSR
EU-EC-1000497495	26/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Urinary tract infection (n/a - Fatal - Results in Death, Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Ashtenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Ibuprofen (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000498404	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death), Rhinorrhoea (3d - Recovered/Resolved -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	Not reported	ICSR
EU-EC-1000498542	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition), Asteroidosis (n/a - Unknown -), COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiomegaly (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Congestive cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hepatic steatosis (n/a - Unknown -), Hypertrophy (n/a - Unknown -), Idiopathic pulmonary fibrosis (n/a - Unknown - Other Medically Important Condition), Lung consolidation (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Pallor (n/a - Unknown -), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Pulmonary hypertension (n/a - Unknown - Other Medically Important Condition), Stenosis (n/a - Unknown -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000498154	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - n/a - n/a - [n/a - n/a - n/a]), (ANGLICA ROOT, GLYCYRRHIZA GLABRA, YOKUKANSAN) (C - n/a - n/a - [n/a - n/a - n/a]), (MEMANTINE) (C - n/a - n/a - [n/a - n/a - n/a]), (RISPERIDONE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000496796	22/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Blindness (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000497163	22/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Death (n/a - Fatal - Results in Death), Thrombocytopenic purpura (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000498966	22/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	Not reported	ICSR

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Region	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Superficial/Intradermal Drug List (Drug Chir - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chir - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
			Professional	European Economic Area	Not available	Not Specified	Female	Not Specified	No	Pallor (n/a - Unknown -), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)			
EU-EC-1000436031	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Female	Not Specified	No	Brain injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (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), Seizure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Syncope (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000443239	21/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-1000413881	20/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Arrhythmia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	ZYPREXA (OLANZAPINE) (C - n/a - n/a - [n/a - n/a - Oral]), BIPERIDEN, BIPERIDEN HYDROCHLORIDE, BIPERIDEN LACTATE (C - n/a - n/a - [n/a - n/a - Oral]), CARBOCISTENE (C - n/a - n/a - [n/a - n/a - Oral]), DIAZEPAM (C - n/a - n/a - [n/a - n/a - Oral]), FLUOXETINE (C - n/a - n/a - [n/a - n/a - Oral]), LORAZEPAM (C - n/a - n/a - [n/a - n/a - Oral]), MAGNESIUM OXIDE (C - n/a - n/a - [n/a - n/a - Oral]), MECLOZAMINE (C - n/a - n/a - [n/a - n/a - Oral]), RIBUABAR (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-1000418377	20/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000427091	20/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Male	Not Specified	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chronic obstructive pulmonary disease (n/a - Recovering/Resolving - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Wheezing (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	RELVAR ELLIPTA (PLUTICASON FURATE, VILANTEROL) (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), MAGNESIUM OXIDE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100040541	18/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	No	Back disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dysstasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000402107	18/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Arrhythmia (n/a - Unknown -), Asthma (n/a - Unknown -), Cardiac failure acute (0d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Epistaxis (n/a - Unknown -), Fatigue (n/a - Unknown -), Hypotension (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	APXIBAN - FILM-COATED TABLET (C - n/a - Not applicable -), ALLOPURINOL (C - n/a - Not applicable -), ZOPICLONE (C - n/a - Not applicable -)	ICSR
EU-EC-1000406617	18/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Male	Not Specified	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ACETYLSALICYLIC ACID (C - Myocardial infarction - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-1000408009	18/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [66d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000393818	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000394206	16/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ACETYLSALICYLIC ACID (C - n/a - n/a - [n/a - n/a - n/a]), AMODARONE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), AMLODIPINE (C - n/a - n/a - [n/a - n/a - n/a]), ATORVASTATIN (C - n/a - n/a - [n/a - n/a - n/a]), FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE (C - n/a - n/a - [n/a - n/a - n/a]), FORMOTEROL FUMARATE, FORMOTEROL FUMARATE DIHYDRATE (C - n/a - n/a - [n/a - n/a - n/a]), FOSFONOPOL SODIUM (C - n/a - n/a - [n/a - n/a - n/a]), FUROSEMIDE (C - n/a - n/a - [n/a - n/a - n/a]), METOPROLOL TARTRATE (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE (C - n/a - n/a - [n/a - n/a - n/a]), SPIRONOLACTONE (C - n/a - n/a - [n/a - n/a - n/a]), THEOPHYLLINE (C - n/a - n/a - [n/a - n/a - n/a]), TICOTRUPILUM OLODATEROL (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000393701	15/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Male	Not Specified	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000393706	15/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral disorder (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Delusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Hallucination, visual (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of control of legs (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000393773	15/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	Death (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000393454	15/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000393136	15/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	Not Specified	No	COVID-19 (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - Product used for unknown indication - Not applicable - [n/a - 1DF] - Unknown), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000393689	14/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	No	Cardiac arrest (0d - Fatal - Results in Death, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	NOT AVAILABLE (C - Blood cholesterol - n/a - [n/a - n/a - Oral]), NOT AVAILABLE (C - Hypertension - n/a - [n/a - n/a - n/a]), LEVOTHYROXINE SODIUM (C - Hypothyroidism - n/a - [n/a - 100ug - Oral])	ICSR
EU-EC-1000396276	14/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	NOT AVAILABLE (C - Blood cholesterol - n/a - [n/a - n/a - Oral]), NOT AVAILABLE (C - Hypertension - n/a - [n/a - n/a - n/a]), LEVOTHYROXINE SODIUM (C - Hypothyroidism - n/a - [n/a - 100ug - Oral])	ICSR
EU-EC-1000396292	14/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	Death (n/a - Fatal - Results in Death), Hypocapnia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000396313	14/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	Not reported	ICSR
EU-EC-1000394993	13/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Oral])	Not reported	ICSR
EU-EC-1000394951	13/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Basal ganglia infarction (n/a - Fatal - Results in Death), Cerebral aneurysm (n/a - Fatal - Results in Death), Cerebral haemorrhage (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Electroencephalogram abnormal (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Intracranial aneurysm (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Pyelonephritis (n/a - Fatal - Results in Death), Subarachnoid haemorrhage (n/a - Fatal - Results in Death), Tracheostomy (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000393168	13/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Ventricular ectopremortality (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000393236	13/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Dementia Alzheimer's type (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000393525	13/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Female	Not Specified	No	Influenza like illness (n/a - Recovered/Resolved -), Purpura (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000393204	12/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	Rash macular (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000393421	12/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Female	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000393464	12/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Life Threatening), Product use issue (n/a - Unknown -)	COVID-19 VACCINE AZTRAZENACA (CHADOX1 NCOV-19) [COVID-19 VACCINE AZTRAZENACA (CHADOX1 NCOV-19)] (S - Immunisation - Unknown - [1d - n/a - n/a]), TOZNAMERAN (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000393596	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	No	Death (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000393691	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [2d - n/a - Intramuscular])	RILUTEK (RILUZOLE) (C - Amyotrophic lateral sclerosis - n/a - [n/a - n/a - Oral]), LOSARTAN, LOSARTAN POTASSIUM (C - Hypertension - n/a - [n/a - n/a - Oral]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP (C - Diabetes mellitus - n/a - [n/a - n/a - Oral]), RISPERIDONE (C - Agitation - n/a - [n/a - n/a - Oral]), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Affective disorder - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-1000393846	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Paresis (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000393643	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000393690	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10003945166	12/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000393153	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000393520	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Foaming at mouth (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10003931612	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10003931576	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	ACENOCOLMAROL (C - n/a - n/a - [n/a - n/a - Oral]), BISOPROLOL FUMARATE, BISOPROLOL FUMARATE ACETYLSALICYLIC ACID, BISOPROLOL HEMIFUMARATE (C - n/a - n/a - [n/a - n/a - Oral]), VALSARTAN (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10003931606	08/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Matase (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10003931819	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	Not Specified	No	Arrhythmia (n/a - Unknown -), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown -), Skin discoloration (n/a - Unknown -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10003931824	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10003931936	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10003931984	08/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10003932097	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [2d - 1DF] - Intramuscular)	ACETYLSALICYLIC ACID, D-LYSINE ACETYLSALICYLIC ACID (C - n/a - n/a -), ALLOPURINOL (C - n/a - n/a -), AMLODIPINE BESILATE, PERINDOPRIL ARGinine, AMLODIPINE, PERINDOPRIL (C - n/a - n/a -), FUROSEMIDE (C - n/a - n/a -), METFORMIN, METFORMIN HYDROCHLORIDE (C - n/a - n/a -), SODIUM POLYSTYRENE SULPHONATE (C - n/a - n/a -)	ICSR
EU-EC-100039321738	08/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10003932463	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000393201869	08/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Chest pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Muscle fatigue (n/a - Unknown -), Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY		

EU Local Number	EY Category/Review Date	Report Type	Primary Source/Confidence	Primary Area/Confidence	Literature Reference	Patient Age Group (at report)	Patient Sex	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000930404	08/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Oedema peripheral (n/a - Unknown - Other Medically Important Condition) Cardiomyopathy (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000930427	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Lip swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Paric attack (n/a - Recovered/Resolved -), Pharyngeal oedema (n/a - Recovered/Resolved - Other Medically Important Condition), Stevens-Johnson syndrome (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	HYDROXYZINE EMBONATE, HYDROXYZINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), LITHIUM CARBONATE (C - n/a - n/a - [n/a - n/a - n/a]), LITHIUM (C - n/a - n/a - [n/a - n/a - n/a]), PROPRANLOL, PROPRANLOL HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), VENLAFAXINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000930463	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Arrhythmia (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - intramuscular])	ASCORBIC ACID (C - n/a - n/a - [n/a - n/a - n/a]), ZINC (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000928790	07/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death) Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - n/a])	XARELTO 20 MG [RIVAROXABAN] (C - n/a - Not applicable -), [ALLIOPURINOL] (C - n/a - Not applicable -), [BISOPROLOL, FUMARATE, BISOPROLOL, HEMIFUMARATE] (C - n/a - Not applicable -), [DOXAZOSIN, DOXAZOSIN MESLATE] (C - n/a - Not applicable -), [METFORMIN HYDROCHLORIDE] (C - n/a - Not applicable -), [SPIRONOLACTONE] (C - n/a - Not applicable -), [THEOPHYLLINE] (C - n/a - Not applicable -), [TORASEMIDE] (C - n/a - Not applicable -)	ICSR
EU-EC-10009291876	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Confusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Mucocutaneous stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10009290805	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Facial asymmetry (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Foaming at mouth (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10009294251	07/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - 2(D)F] - n/a)	Not reported	ICSR
EU-EC-10009272770	06/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1d - n/a - intramuscular])	JANUVIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), LANTUS SOLOSTAR [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - Oral]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Oral]), [ALUMINUM HYDROXIDE GEL, DRIED, MAGNESIUM CARBONATE, SODIUM CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE, SODIUM CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE GEL, DRIED USP, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, SODIUM ALGINATE, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALUMINUM HYDROXIDE GEL, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, CALCIUM ALGINATE, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, CALCIUM ALGINATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - Oral]), [CARBAMAZEPINE] (C - n/a - n/a - [n/a - n/a - Oral]), [CARBOMER, CARBOMER 974P] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ESTRODIOL] (C - n/a - n/a - [n/a - n/a - Vaginal]), [FENTANYL] (C - n/a - n/a - [n/a - n/a - Transdermal]), [FLUTICASON, FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL, XINIFOATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - Sublingual]), [IBUPROFEN, IBUPROFEN SODIUM BIPHENATE] (C - n/a - n/a - [n/a - n/a - Oral]), [IPRATROPIUM BROMIDE, SALBUTAMOL, SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [ISOPAGLIL, HUSK] (C - n/a - n/a - [n/a - n/a - Oral]), [KETOPROFEN, KETOPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - Topical]), [LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - Oral]), [METOPROLOL, SUCCINATE, METOPROLOL TARTRATE, METOPROLOL, TARTRATE PH. EUR.] (C - n/a - n/a - [n/a - n/a - Oral]), [MOMETASONE FURATE, MOMETASONE FURATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Nasal]), [MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [ORPHENADRINE CITRATE, PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [PITOFENONE HYDROCHLORIDE, METAMIZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM, SODIUM, MACRODOL 3550, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACRODOL 3550] (C - n/a - n/a - [n/a - n/a - Oral]), [PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE, PROCHLORPERAZINE MALEATE BP, PROCHLORPERAZINE MESILATE] (C - n/a - n/a - [n/a - n/a - Oral]), [QUETIAPINE] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral])	
EU-EC-10009272772	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Coronavirus test positive (n/a - Unknown -), Cough (n/a - Not Recovered/Not Resolved - Caused/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Not Resolved - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009279400	06/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Peripheral vascular disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10009279537	06/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009279540	06/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009279607	06/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009280427	06/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - intramuscular])	Not reported	ICSR
EU-EC-10009280667	06/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F] - intramuscular)	Not reported	ICSR
EU-EC-10009280452	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009281110	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)F] - n/a)	Not reported	ICSR
EU-EC-10009281731	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Headache (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009281736	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009281820	05/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009281893	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Fatigue (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 -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009282837	05/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)F] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009283199	05/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [ALLIOPURINOL] (C - n/a - n/a - [n/a - 300mg - Oral]), [FAMOTIDINE] (C - n/a - n/a - [n/a - 20mg - Oral]), [FLUVASTATIN SODIUM] (C - n/a - n/a - [n/a - 80mg - Oral]), [FOSFONORIL, SODIUM, HYDROCHLOROHAZIDE, HYDROCHLOROHAZIDE, FOSFONORIL] (C - n/a - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL, TARTRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RILMENIDINE, RILMENIDINE DIHYDROGEN PHOSPHATE] (C - n/a - n/a - [n/a - 1mg - Oral])	ICSR
EU-EC-10009286003	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009286336	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009286370	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 1(D)F] - intramuscular)	Not reported	ICSR
EU-EC-10009286305	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(D)F] - intramuscular)	Not reported	ICSR
EU-EC-10009286743	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Sepsis (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009284356	02/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009282056	01/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Loss of consciousness (n/a - Unknown - Life Threatening - Other Medically Important Condition) Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Monoplegia (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009282299	01/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 5mL - intramuscular])	Not reported	ICSR
EU-EC-10009282386	01/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Suspected counterfeit product (n/a - Unknown -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009282669	01/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (2d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100092829163	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Facial paralysis (4d - Recovered/Resolved - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009281903	01/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Suspected counterfeit product (n/a - Unknown -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009282350	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ELUGIS (APIXABAN) (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009283159	01/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009283162	01/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009280696	30/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10009280743	30/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (n/a - Recovered/Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	EDOXABAN [EDOXABAN] (C - n/a - n/a - [n/a - 30mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESLATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [LANOPROLOL] (C - n/a - n/a - [n/a - 20mg - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - 5mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - n/a]), [SMECTONE] (C - n/a - n/a - [n/a - 125mg - n/a])	ICSR
EU-EC-10009280951	30/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10009281309	30/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009281319	30/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No				

EU Local Number	EY Category/Report Date	Report Type	Primary Source/Qualification	Primary Source/Country for Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
											ZOLEDRONIC ACID (ZOLEDRONIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL] (C - n/a - n/a -), [PENTANYL] (C - n/a - n/a - [n/a - 200ug - n/a]), [METOCLOPRAMIDE, METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [PARACETAMOL, PARACETAMOL PH. EUR., PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - 500mg - n/a])		CSR
EU-EC-1000187966	28/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU-EC-100011245	28/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000117393	28/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR	
EU-EC-1000117198	28/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR	
EU-EC-1000117258	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	ENTRESTO (VALSARTAN SACUBITRIL) (C - n/a - n/a - [n/a - n/a - Oral]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - n/a - n/a - [n/a - n/a - Oral]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - Oral]), [ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - Oral]), [AMODARONE, AMODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - Oral]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - Oral])		CSR
EU-EC-1000115198	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Asthma (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypersensitivity (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown -), Peripheral swelling (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000115857	28/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Mucositis (n/a - Unknown -)	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])	[GOSERELEIN] (C - Prostate cancer - Not applicable -)	CSR	
EU-EC-1000117820	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Adult	Male	Abdominal pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000117803	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000118599	28/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Cardiac failure acute (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 1DF] - n/a)	Not reported	CSR	
EU-EC-1000114215	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU-EC-1000114613	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Erythema (n/a - Recovered/Resolved -), Urticaria (n/a - Fatal - Results in Death, Caused/Not Resolved/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ESOMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL DECANATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE, TORASEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-1000114624	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Palpitations (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000115089	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 1DF] - Intramuscular)	[ESOMEPRAZOLE] (ESOMEPRAZOLE) (C - n/a - n/a -), [COLTIDIPRINE] (C - n/a - n/a -), [COLICLALFEROL] (C - n/a - n/a -), [D,L-lysine ACETYL SALICYLATE] (C - n/a - n/a -), [GLYCERYL TRINITRATE] (C - n/a - n/a -), [TIAPRIDE HYDROCHLORIDE] (C - n/a - n/a -)	CSR	
EU-EC-1000115115	25/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[METHOTREXATE (METHOTREXATE)] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [ESGITALOPRAM, ESGITALOPRAM OXALATE] (C - n/a - n/a -), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, RAMPREL] (C - n/a - n/a -), [PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-1000132718	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000115301	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000115308	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000115200	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Unknown -), Myocardial infarction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000116382	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOVOMIX 30 FLEXPEN 100 UNITS/ml SUSPENSION FOR INJECTION IN PRE-FILLED PEN (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a]), [BARNIDIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 15mg - n/a]), [MORPHINE, MORPHINE POLYSTYRENE CO-INVOLUBENZENE] SULFONATE, MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE, MORPHINE SULFATE PH. EUR.] (C - Spinal disorder - n/a - [n/a - 20mg - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 10mg - n/a])	CSR	
EU-EC-1000115225	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Asthma (n/a - Unknown -), Condition aggravated (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Fall (n/a - Unknown -), Neck pain (n/a - Unknown -), Pain (n/a - Not Recovered/Not Resolved -), Parosmia (n/a - Unknown -), Peripheral venous disease (n/a - Unknown -), Pyrexia (n/a - Unknown -), Spinal disorder (n/a - Unknown -), Urinary retention (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[DIPOFASSUM CLORAZEPATE] (C - Fentanyl - n/a - [n/a - 1DF] - Oral), [SETRALINE HYDROCHLORIDE] (C - Fentanyl - n/a - [n/a - 1DF] - Oral)	CSR	
EU-EC-1000128248	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Primary amenorrhoea (n/a - Unknown - Other Medically Important Condition), Anxiety (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), Chest discomfort (n/a - Fatal - Results in Death, Other Medically Important Condition), Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Discomfort (n/a - Fatal - Results in Death, Other Medically Important Condition), Discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Haemoptysis (n/a - Fatal - Results in Death, Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular), COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 1DF] - Intramuscular)	[DIPOFASSUM CLORAZEPATE] (C - Fentanyl - n/a - [n/a - 1DF] - Oral), [SETRALINE HYDROCHLORIDE] (C - Fentanyl - n/a - [n/a - 1DF] - Oral)	CSR	
EU-EC-1000129645	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000130399	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU-EC-1000130435	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000112551	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Arthralgia (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Hypokinesia (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000112553	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Dyspepsia (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Haemorrhage (n/a - Fatal - Results in Death), Influenza like illness (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Nasopharyngitis (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])	Not reported	CSR	
EU-EC-1000119275	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Lip pain (n/a - Unknown -), Lip swelling (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR	
EU-EC-1000116386	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - 150mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [GLIMEPIRIDE] (C - n/a - n/a - [n/a - 2mg - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - 5mg - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - 250mg - n/a])	CSR	
EU-EC-1000112745	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000113670	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000113800	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - n/a)	OLANZAPINE TEVA (OLANZAPINE) (C - Schizophrenia - n/a - [n/a - 5mg - Oral]), TREVICTA (PALIPERIDONE PALMATE) (C - Mental disorder - n/a - [n/a - 350mg - Intramuscular])	CSR	
EU-EC-1000111698	24/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	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 - [1d - n/a - n/a])	Not reported	CSR	
EU-EC-1000111456	23/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Subcutaneous])	Not reported	CSR	
EU-EC-1000111236	23/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU-EC-1000111947	23/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-1000111941	23/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10001120425	23/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Cerebrovascular accident (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dysarthria (n/a - Fatal - Results in Death), Dysphagia (n/a - Fatal - Results in Death), Hemiparesis (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-10001120428	23/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (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])	Not reported	CSR	
EU-EC-1000097257	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Asthma (n/a - Unknown - Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiacopathy - n/a - [n/a - n/a - n/a]), [SPRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-1000097673	22/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Bradycardia (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fat (n/a - Unknown - Other Medically Important Condition), Fat (n/a - Unknown - Other Medically Important Condition), Gas entry (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Ischaemic stroke (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - n/a - [n/a - 1g - Oral])	CSR	
EU-EC-1000097996	22/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU-EC-1000098811	22/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	

EU Local Number	EY Category Review Date	Report Type	Primary Source Qualification	Primary Country Regulatory Reference	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chn - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chn - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
						Years				Death (n/a - Fatal - Results in Death), Dehydration (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death), Chest pain (n/a - Fatal - Results in Death), Cold sweat (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Fatal - Results in Death), Discomfort (n/a - Fatal - Results in Death)		[LAMOTRIGINE] (C - n/a - n/a - [n/a - 100mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 50mg - n/a])	
EU-EC-10009024872	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Cold sweat (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Fatal - Results in Death), Discomfort (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009024822	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10009024933	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Abnormal pain upper (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009026878	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009027385	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	SEEBRI BREEZHALER (OLYCOPYRONIUM BROMIDE) (C - n/a - n/a -), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE HYDRATE, FORMOTEROL FUMARATE DIHYDRATE PH EUR, BECLOMETASONE DIPROPIONATE PH EUR, FORMOTEROL FUMARATE DIHYDRATE PH EUR, BECLOMETASONE DIPROPIONATE PH EUR, FORMOTEROL FUMARATE DIHYDRATE, BECLOMETASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a -), [FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a -), [PVOIDONE K25, THEOPHYLLINE, THEOPHYLLINE ANHYDROUS] (C - n/a - n/a -), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a -)	ICSR
EU-EC-10009030524	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009030839	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	ZOLEDRONIC ACID (ZOLEDRONIC ACID) (C - n/a - n/a - [n/a - 3.5mg - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [Dexamethasone] (C - n/a - n/a - [n/a - n/a - n/a]), [NAPROXEN, NAPROXEN SODIUM, NAPROXEN SODIUM ANHYDROUS] (C - n/a - n/a - [n/a - 550mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - Oral]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a])	ICSR
EU-EC-10009111713	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009120203	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10009186147	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009186336	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Throat irritation (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009186473	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Mental impairment (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009186543	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	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), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009187172	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009187069	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009187409	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009187417	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Pulvic venous thrombosis (n/a - Not Recovered/Not Resolved -), Thrombosis (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009187420	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009187431	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Thrombosis (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091872417	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	LANTUS (INSULIN GLARGINE) (C - n/a - n/a - [n/a - n/a - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [SODIUM VALPROATE, VALPROIC ACID] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10009172537	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10009172542	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	[ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a -), [LAMOTRIGINE] (C - n/a - n/a -)	ICSR
EU-EC-10009187378	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009187470	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100091856109	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091857036	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091857091	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Circulatory collapse (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Praxycopy (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	[CALCIUM, CALCIUM CARBONATE, CALCIUM CITRATE, CALCIUM K0N] (C - n/a - n/a -), [COLECALCIFEROL] (C - n/a - n/a -), [DEXAMETHASONE, DEXAMETHASONE DISODIUM PHOSPHATE, DEXAMETHASONE PHOSPHATE, DEXAMETHASONE SODIUM PHOSPHATE] (C - n/a - n/a -), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a -), [MIRTAZAPINE] (C - n/a - n/a -), [PROTHIPIPERIDYL HYDROCHLORIDE, PROTHIPIPERIDYL HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a -), [RISPERIDONE] (C - n/a - n/a -), [INSULIN CORE 25 (INSULIN HUMAN), INSULIN HUMAN (RNA), INSULIN HUMAN (ISOPHANE RNA), INSULIN HUMAN REGULAR (RNA)] (C - n/a - n/a -), [ACETYSALICYLIC ACID] (C - n/a - n/a -), [AMLODIPINE, INDAPAMIDE, FERINDOPROL, ARGININE, INDAPAMIDE, AMLDOPINE BESILATE, PERINDOPROL, ARGININE] (C - n/a - n/a -), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a -), [NEBIVOLOL] (C - n/a - n/a -), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a -)	ICSR
EU-EC-100091857209	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100091857896	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091858957	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091859000	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Headache (n/a - Not Recovered/Not Resolved -), Visual impairment (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100091859361	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardio-respiratory arrest (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])	Not reported	ICSR
EU-EC-100091859362	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	ENTRESTO [VALSARTAN SACLIBTEL] (C - Cardiac failure - Dose not changed - [n/a - n/a - Oral])	ICSR
EU-EC-100091859365	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[QUETIAPINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100091859368	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CARVEDILOL] (C - Blood pressure abnormal - n/a - [n/a - n/a - n/a]), [HYDROCHLORAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [SMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100091859384	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100091859389	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	XARELTO [RIVAROXABAN] (C - Anal fistula - n/a - [n/a - n/a - n/a]), [BENDROFLUMETHAZIDE, POTASSIUM CHLORIDE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - n/a - Oral]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - Oral]), [SMVASTATIN] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-100091859384	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Fatal - Results in Death, Life Threatening), Agitation (n/a - Fatal - Results in Death, Life Threatening), Anorexia (n/a - Fatal - Results in Death, Life Threatening), Asthma (n/a - Fatal - Results in Death, Life Threatening), Balance disorder (n/a - Fatal - Results in Death, Life Threatening), Confusional state (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening), Nervous system disorder (n/a - Fatal - Results in Death, Life Threatening), Oxygen saturation decreased (n/a - Fatal - Results in Death, Life Threatening), Palsy (n/a - Fatal - Results in Death, Life Threatening), Speech disorder (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000918593818	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Mucosa (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BENZONATATE] (C - n/a - n/a - [n/a - 300mg - Oral]), [NAPROXEN] (C - n/a - n/a - [n/a - 1000mg - Oral])	ICSR
EU-EC-100091859397	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000918594056	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000918594057	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009185940729	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved -), Peripheral swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009185940723	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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])	Not reported	ICSR
EU-EC-1000918594090	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000918594094	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	[ALPRAZOLAM] (C - n/a - n/a -)	ICSR
EU-EC-100091859407	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009185940539	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diabetic complication (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperkalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[PYRIDOSTIGMINE, PYRIDOSTIGMINE BROMIDE] (C - Myasthenia gravis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100091859408	07/0												

EU Local Number	EY Category Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Purpose	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
						Years				Blood glucose abnormal (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Disorientation (n/a - Fatal - Results in Death), Eye pain (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Neuroendocrine carcinoma of the skin (n/a - Fatal - Results in Death), Oedema peripheral (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Varicose ulceration (n/a - Fatal - Results in Death), Visual impairment (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)			
EU-EC-1000895238	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	ACEYLSALICYLIC ACID (C - n/a - n/a -), ALPRAZOLAM (C - n/a - n/a -), AMLODIPINE, AMLODIPINE BESILATE (C - n/a - n/a -), GLYCERYL TRINITRATE (C - n/a - n/a -), NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE (C - n/a - n/a -), SIMVASTATIN (C - n/a - n/a -), SPIRONOLACTONE (C - n/a - n/a -), TRIMETAZIDINE DIHYDROCHLORIDE (C - n/a - n/a -)	ICSR
EU-EC-1000895971	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000897625	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (S1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000897652	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (S1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000897961	03/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000898353	02/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (D1 - Fatal - Results in Death), Death (D1 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	METHOTREXATE (METHOTREXATE) (C - Psoriatic arthropathy - n/a - [n/a - n/a]), METHYLPREDNISOLONE (C - n/a - n/a - n/a)	ICSR
EU-EC-1000898734	02/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (D1 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008987429	02/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (S1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL, BESILATE (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE (C - n/a - n/a - [n/a - 40mg - n/a]), ALLOPRINOL (C - n/a - n/a - [n/a - 300mg - Oral]), BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE (C - n/a - n/a - [n/a - 2.5mg - n/a]), ENOXAPARIN SODIUM (C - n/a - n/a - [n/a - 6mL - Subcutaneous]), FUROSEMIDE (C - n/a - n/a - [n/a - n/a - Oral]), GLUCILAZIDE (C - n/a - n/a - [n/a - 60mg - Oral]), GLYCEROL (C - n/a - n/a - [n/a - n/a - Rectal]), LACTULOSE, LACTULOSE CRYSTALLINE (C - n/a - n/a - [n/a - n/a - Oral]), PALMITIC ACID (C - n/a - n/a - [n/a - n/a - Rectal]), POTASSIUM CHLORIDE (C - n/a - n/a - [n/a - 600mg - Oral]), STEARIC ACID (C - n/a - n/a - [n/a - n/a - Rectal]), TRIMETAZIDINE DIHYDROCHLORIDE (C - n/a - n/a - [n/a - 35mg - Oral])	ICSR
EU-EC-10008970115	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Central venous thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Breast (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000897294	01/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abdominal pain upper (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Nausea (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (2d - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (2d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1d - 1DF - Intramuscular])	Not reported	ICSR
EU-EC-1000898393	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008980059	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008980736	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008980740	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 3mL - n/a])	PHENPROLOLUMON (C - n/a - n/a -)	ICSR
EU-EC-10008982223	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008984654	31/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008984700	31/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	ATORVASTATIN (C - n/a - n/a - [n/a - n/a - n/a]), BISOPROLOL HEMIFUMARATE (C - n/a - n/a - [n/a - n/a - n/a]), (D,L)LYSINE ACETYLSALICYLATE (C - Cerebrovascular accident - Not applicable - [n/a - n/a - n/a]), MIRTAPINE (C - n/a - n/a - [n/a - n/a - n/a]), SPIRONOLACTONE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008984746	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008982102	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Body temperature increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnea (n/a - Fatal - Results in Death), Marriage (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008913457	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	XLTOPY (BRIQUILITIDE, NOLIN DEGLUCIDE) (C - n/a - n/a -), AMLODIPINE, AMLODIPINE, PERINDOPRIL, NINONE, NINONE, AMLODIPINE BESILATE, PERINDOPRIL, ARGININE (C - n/a - n/a -), BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE (C - n/a - n/a -), DIGOXIN (C - n/a - n/a -), DIOXANOLIN, DIOXANOLIN MESILATE (C - n/a - n/a -), METFORMIN HYDROCHLORIDE (C - n/a - n/a -), RILMENIDINE, RILMENIDINE DIHYDROGEN PHOSPHATE (C - n/a - n/a -), TIOTROPOLIUM, TIOTROPOLIUM BROMIDE, TIOTROPOLIUM BROMIDE MONOHYDRATE (C - n/a - n/a -), WARFARIN SODIUM, WARFARIN SODIUM CLATHRATE (C - n/a - n/a -)	ICSR
EU-EC-10008981429	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008915490	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100089816756	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008919303	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Deep vein thrombosis (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008919666	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (15d - Fatal - Results in Death), General physical health deterioration (16d - Fatal - Results in Death), Malaise (16d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008919899	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Pulmonary embolism (5d - Recovered/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF - Intramuscular])	Not reported	ICSR
EU-EC-10008920331	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	COAPROVEL, HYDROCHLOROTHIAZIDE, IRRESARTAN (C - n/a - n/a -), XARELTO 20 MG FILM COATED TABLETS (RIVAROXABAN) (C - n/a - n/a -), AMODARONE, AMODARONE HYDROCHLORIDE (C - n/a - n/a -), METOPROLOL FUMARATE (C - n/a - n/a -)	ICSR
EU-EC-10008920316	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (1d - Fatal - Results in Death), Somnolence (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008920358	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008925258	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Death (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition), Meckel's diverticulum syndrome (n/a - Unknown - Other Medically Important Condition), Premature baby (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR])	CRISABOROLE (C - Dermatitis atopica - n/a - [n/a - Transplacental]), LORATADINE (C - Hypersensitivity - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10008922915	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnea (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008978040	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Malaise (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])	Not reported	ICSR
EU-EC-10008978183	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008976703	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (S1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (S1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008980368	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal pain (n/a - Fatal - Results in Death), Angiopathy (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a - More in ICSR])	APIXABAN (APIXABAN) (C - n/a - n/a -), BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE (C - n/a - n/a -), CANDESARTAN (C - n/a - n/a -), DIGOXIN (C - n/a - n/a -), EZEZITIMBE (C - n/a - n/a -), FERROUS FUMARATE (C - n/a - n/a -), FUROSEMIDE (C - n/a - n/a -), INCISORABLE (C - n/a - n/a -), INACETAMOL (C - n/a - n/a -), ROBUVASTATIN, ROBUVASTATIN CALCIUM (C - n/a - n/a -), TITOLOL, TARLUPROST (C - n/a - n/a -)	ICSR
EU-EC-10008980372	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Body temperature increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (D1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Delirium (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disorientation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008980648	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (D1 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008979093	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (D1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008979118	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (S1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	TEMOZOLOMIDE ACCORD (TEMOZOLOMIDE) (C - n/a - n/a - [n/a - n/a - Oral]), OCTREOTIDE, OCTREOTIDE ACETATE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008978212	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Disorientation (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Sexual dysfunction (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	AZELICT (RASAGLINE, RASAGLINE MESILATE) (C - n/a - n/a - [n/a - n/a - n/a]), CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL, BESILATE (C - n/a - n/a - [n/a - n/a - n/a]), JANUVA (BITAGLIPIN, BITAGLIPIN PHOSPHATE, BITAGLIPIN PHOSPHATE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), TRESIBA (INSULIN DEGLUCIDE) (C - n/a - n/a - [n/a - n/a - n/a]), CARBAMAZEPINE, CARBAMAZEPINE (PH. EUR.) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008978347	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (D1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100089786173	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Death (D1 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008978663	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Acquired haemophilia (n/a - Fatal - Results in Death), Anti body (V) antibody positive (n/a - Fatal - Results in Death), Atrial fibrillation (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	ALLOPRINOL (C - Gout - n/a - [n/a - n/a - Oral]), BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE (C - Cardiac failure - n/a - [n/a - n/a - Oral]), FUROSEMIDE (C - Cardiac failure - n/a - [n/a - n/a - Oral]), INACETAMOL (C - n/a - n/a - [n/a - n/a - Oral]), ZINCLOXIDE (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008978618	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Central haemorrhage (n/a - Fatal - Results in Death), Corns (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Nausea (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])	PARACETAMOL, PARACETAMOL, CODICINE PHOSPHATE HEMIHYDRATE (C - Pain - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10008978618	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Vomiting (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [2d - 2DF - Intramuscular])	Not reported	ICSR
EU-EC-10008978332	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	

EU Local Number	EY Category Review Date	Report Type	Primary Source Country for Regulatory Purposes	Literature Reference	Patent Age Group (as per report)	Patent Sex	Patent Child	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form			
								Lip swelling (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pharyngeal swelling (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown -), Pyrexia (n/a - Unknown -), Seizure (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Swelling face (n/a - Unknown -), Swollen tongue (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Caused/Not Reported/Other Medically Important Condition)		HYDROCHLOROTHIAZIDE (C - n/a - n/a - [n/a - 25mg - n/a]), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Antidepressant therapy - n/a - [n/a - 100mg - n/a]), VITAMIN D3 (C - n/a - n/a - [n/a - 1000IU] - n/a)				
EU-EC-1000871541	25/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000871619	25/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Cardiac failure acute (S4 - Fatal - Results in Death), Death (S4 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000871663	25/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000871691	25/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000871820	25/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (S4 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000872340	25/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (S4 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	ICACINOCOLMAROL (C - n/a - n/a -), GLUCALZIDE (C - n/a - n/a - [n/a - 60mg - n/a]), INDAPARIDE, PERNIDOPRIL (C - n/a - n/a -), INDAPARIDE (C - n/a - n/a - [n/a - 1.5mg - n/a]), MELOXICAM (C - n/a - n/a - [n/a - 15mg - n/a]), METFORMIN HYDROCHLORIDE (C - n/a - n/a - [n/a - 500mg - n/a]), PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - n/a - n/a - [n/a - 40mg - n/a]), QUETIAPINE, QUETIAPINE FUMARATE (C - n/a - n/a - [n/a - 25mg - n/a])	ICSR	
EU-EC-1000877390	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Reported/Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-1000877520	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000877529	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Adult	Female	No	Breast pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000877556	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Mucosa (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000877826	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000878289	24/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000874298	23/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000874319	23/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000875274	23/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000875270	23/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000875756	21/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown -), Cardiac death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000872913	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (S4 - Fatal - Results in Death, Caused/Not Reported/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE (C - n/a - n/a - Drug withdrawn -), GLYCERYL TRINERATE (C - n/a - n/a - [n/a - n/a - Transdermal]), POVIDONE K25, THEOPHYLLINE, THEOPHYLLINE ANHYDROUS (C - n/a - n/a -), SPRINOLACTONE (C - n/a - n/a - [n/a - n/a - Oral])	ICSR	
EU-EC-1000873230	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000873338	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	ARIPRAZOLE (ARIPRAZOLE) (C - n/a - n/a -)	ICSR
EU-EC-1000873396	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000873736	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000871207	20/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Oropharyngeal pain (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000871457	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Erythema (n/a - Fatal - Results in Death), Erythema multiforme (n/a - Fatal - Results in Death), Erythema nodosum (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE (C - Antenna - n/a - [n/a - n/a - n/a]), ESTRADIOL (C - Hormone replacement therapy - n/a - [n/a - n/a - n/a]), FLUKETINE, FLUKETINE HYDROCHLORIDE (C - Depressed mood - n/a - [n/a - n/a - n/a]), LEVONORGESTREL, LEVONORGESTREL MCRONIBEDYL (C - n/a - n/a - [n/a - n/a - n/a]), OMEPRAZOLE (C - Dyspepsia - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000871570	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (S4 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000871646	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (S4 - Fatal - Results in Death, Caused/Not Reported/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000871706	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (S4 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	ICSR	
EU-EC-1000872095	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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])	Not reported	ICSR	
EU-EC-1000869817	19/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000870301	19/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Reported/Other Medically Important Condition), Pulmonary embolism (S3 - Fatal - Results in Death, Life Threatening, Caused/Not Reported/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 - n/a - [n/a - n/a - Intramuscular])	EXELON (RIVASTIGMINE) (C - Vascular dementia - n/a - [n/a - 1(D)F - Cutaneous]), ACETYSALICYLIC ACID (C - Anticoagulant therapy - n/a - [n/a - 1(D)F - Oral]), FUROSEMIDE, FUROSEMIDE SODIUM (C - n/a - n/a - [n/a - 1(D)F - Oral]), GLYCERYL TRINERATE (C - n/a - n/a - [n/a - 1(D)F - Cutaneous]), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Depression - n/a - [n/a - 50mg - Oral])	ICSR	
EU-EC-1000870096	19/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Eczema (n/a - Unknown -), Respiratory disorder (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000870414	19/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	INSULIN ASPART (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - Subcutaneous]), TOULEO SOLOSTAR (INSULIN GLARGINE) (C - n/a - n/a - [n/a - 1.5mL - Subcutaneous]), AMLODIPINE, AMLODIPINE BESILATE (C - n/a - n/a - [n/a - 10mg - Oral]), COLECALCIFEROL (C - n/a - n/a - [n/a - n/a - Oral]), HYDROCHLOROTHIAZIDE (C - n/a - n/a - [n/a - 25mg - Oral]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - n/a - n/a - [n/a - 2.5mg - Oral]), SALBUTAMOL, SALBUTAMOL SULFATE (C - n/a - n/a - [n/a - 800ug - Oral])	ICSR	
EU-EC-1000870571	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000870799	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (S4 - Fatal - Results in Death, Caused/Not Reported/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000871034	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	No	Death (S4 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000869056	18/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	INSULATARD (INSULIN HUMAN, INSULIN HUMAN (RDN), INSULIN HUMAN (ISOPHANE (RDN)) (C - n/a - n/a - [n/a - n/a - n/a]), JANUVIA (SITAGLIPIN, SITAGLIPIN PHOSPHATE, SITAGLIPIN PHOSPHATE MONOHYDRATE) (C - n/a - n/a - [n/a - 50mg - n/a]), ACETYSALICYLIC ACID (C - n/a - n/a - [n/a - 75mg - n/a]), ALLOPURINOL (C - n/a - n/a - [n/a - 300mg - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - n/a - n/a - [n/a - 10mg - n/a]), ATORVASTATIN (C - n/a - n/a - [n/a - 40mg - n/a]), GLYCERYL TRINERATE, GLYCERYL TRINERATE SOLUTION (C - n/a - n/a - [n/a - n/a - n/a]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP (C - n/a - n/a - [n/a - 500mg - n/a]), VALSARTAN, HYDROCHLOROTHIAZIDE (C - n/a - n/a - [n/a - 1(D)F - n/a])	ICSR	
EU-EC-1000869110	18/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Not Reported/Other Medically Important Condition), Hemoglobin decreased (n/a - Fatal - Results in Death, Caused/Not Reported/Other Medically Important Condition), Lymphoedema (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Peripheral swelling (n/a - Unknown -), Swelling (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000869079	18/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(D)F - Intramuscular])	Not reported	ICSR	
EU-EC-1000869247	18/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Not Reported/Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000869241	18/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Recovering/Resolving -), Haematochezia (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Somnolence (n/a - Recovering/Resolving -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000869203	17/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	No	Death (n/a - Fatal - Results in Death), Ischaemia (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [2d - n/a - Intramuscular])	JARDIANCE (EMPAFLIZOZIN) (C - n/a - n/a - [n/a - n/a - Oral]), DICYCLOFENAC POTASSIUM (C - n/a - n/a - [n/a - n/a - Oral]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP (C - n/a - n/a - [n/a - n/a - n/a]), FAMSILOSIN HYDROCHLORIDE, DUTASTERIDE (C - n/a - n/a - [n/a - n/a - n/a]), WARFARIN SODIUM (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-1000869204	17/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Exposure to SARS-CoV-2 (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	ACETYSALICYLIC ACID (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a]), ALPRAZOLAM (C - Dementia - n/a - [n/a - n/a - n/a]), HYDROCHLOROTHIAZIDE, RAMPRIL (C - Hypertension - n/a - [n/a - n/a - n/a]), TIAPRIDE, TIAPRIDE HYDROCHLORIDE (C - Dementia - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000869269	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Brain death (n/a - Unknown - Other Medically Important Condition), Brain injury (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Brain oedema (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Pneumonia aspiration (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Not Reported/Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000869720	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	EDOXABAN (EDOXABAN) (C - n/a - n/a - [n/a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - n/a - n/a - [n/a - n/a - n/a]), ATORVASTATIN (C - n/a - n/a - [n/a - n/a - n/a]), COLECALCIFEROL, CALCIUM CARBONATE (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMPARAMINE, TRAMPARAMINE MALEATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000869726	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DONEPEZIL] (C - n/a - n/a - [n/a - n/a - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOPERAMIDE, LOPERAMIDE HYDROCH		

EU Local Number	EY Category/Report Date	Report Type	Primary Source/Qualification	Primary Country/Regulatory Purpose	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chir - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Chir - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
											TRAJENTA 5 MG FILM-COATED TABLETS [LINALGPTIN] (C - n/a - Dose not changed - [n/a - 5mg - n/a]), TRITICO RET TBL 150MG [NOT AVAILABLE] (C - n/a - Dose not changed - [n/a - 50mg - n/a]), ACETYSALICYLIC ACID (C - n/a - Dose not changed - [n/a - 100mg - n/a]), [AMLODIPINE BESILATE] (C - n/a - Dose not changed - [n/a - 5mg - n/a]), [COLECALFEROL] (C - n/a - Dose not changed - [n/a - 35[9g] - n/a]), [METAZOLE SODIUM MONOHYDRATE] (C - Pan - Dose not changed - [n/a - 25[9g] - n/a]), [RISPERIDONE] (C - Restlessness - Dose not changed - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000864255	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])		ICSR
EU-EC-1000864903	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Life Threatening), Dementia (n/a - Not Recovered/Not Resolved - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000864925	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000864673	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	COVID-19 (20) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000864941	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000864942	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000864940	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000864967	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-1000864970	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Asites (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -), Hot flush (n/a - Not Recovered/Not Resolved -), Lymphoedema (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000864704	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000864955	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[ALLOPRINOX] (C - n/a - n/a - [n/a - 100mg - Oral]), [BISOPROLOL FLUMARATE, BISOPROLOL, FUMARATE, ACETYSALICYLIC ACID, BISOPROLOL, HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [ECLECALFEROL] (C - n/a - n/a - [100[0g] - n/a]), [DOXAZOSIN, DOXAZOSIN MESLATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 50mg - Oral]), [VINPOCETINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000864982	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Hypoxemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000865009	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	[AMLODIPINE, RAMPREL] (C - Hypertension - n/a - [n/a - 1[DF] - Oral]), [NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - 2.5mg - Oral])	ICSR
EU-EC-1000865128	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[PREDNISOLONE] (C - COVID-19 - n/a - [n/a - 40mg - n/a])	ICSR
EU-EC-1000862971	13/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - n/a])	Not reported	ICSR
EU-EC-1000863114	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000863148	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	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 - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000863070	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000863030	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	Not reported	ICSR
EU-EC-1000863783	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000862033	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000861777	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000863032	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000864603	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Death (n/a - Fatal - Results in Death), Platelet count decreased (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000863422	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dysphagia (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[CHOLB BIFENOLATE, SIKASTATIN] (C - n/a - n/a - [n/a - n/a - Oral]), [MAGNESIUM OXYTRICHOLOIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [VALSARTAN] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-1000865685	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000867581	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000867951	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Abdominal pain (n/a - Unknown -), Asthma (n/a - Unknown -), COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown -), Oxygen saturation decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), PCO2 abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Renal failure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sudden hearing loss (n/a - Unknown - Other Medically Important Condition), Tinnitus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BERENIDA REPENS] (C - Prostatic disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000862111	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000865040	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000861072	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Mucosa (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000861117	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Asthma (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10008611561	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	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])	Not reported	ICSR
EU-EC-10008611629	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	COVID-19 (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008611632	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008611638	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Cardiac discomfort (n/a - Unknown -), Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Performance status decreased (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008611639	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000861246	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008612921	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Death neonatal (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Premature baby (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Transplacental])	[ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALFEROL, CALCIUM] (C - Supplementation therapy - n/a - [n/a - 1[DF] - n/a]), [ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - Pregnancy - n/a - [n/a - 1[DF] - n/a]), [CALCIUM CARBONATE, CALCIUM CARBONATE P/ EUR] (C - Gastroesophageal reflux disease - n/a - [n/a - 500mg - n/a]), [FLUTICASON PROPIONATE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pan - n/a - [n/a - n/a - n/a]), [TRIAMCLOLONE] (C - Dermatitis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008613741	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Aphasia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Gas malady (n/a - Unknown - Other Medically Important Condition), Hyperemia (n/a - Unknown - Other Medically Important Condition), Incontinence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL, BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-1000861396	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000861629	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000862818	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Tumour thrombosis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [BETAXOLOL HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [MESALAZINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [POLYSACCHARIDE IRON COMPLEX] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-1000863932	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Chest discomfort (n/a - Recovered/Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008638242	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000863869	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1[DF] - Intramuscular]), [CYANEMAZINE] (S - n/a - n/a - [n/a - 10mg - n/a]), [DOMPERIDONE] (S - n/a - n/a - [n/a - 30mg - n/a]), [ESICHTALOPRAM] (S - n/a - n/a - [n/a - 10mg - n/a])	Not reported	ICSR
EU-EC-10008638970	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10008639087	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008639182	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008637007	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000863723	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [8d - n/a - n/a])	[ELIGIUS [ARXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ZYPERA [OLANZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER, CARBOMER 980] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE MONOHYDRATE] (C - n/a - n/a - [n	

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Country for Regulatory Purposes	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/ Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000569949	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Vascular anastomosis (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	ELIQUIS (APIXABAN) (C - n/a - n/a - [n/a - n/a - n/a]), (CHLORZOXAZONE) (C - n/a - n/a - [n/a - n/a - n/a]), (CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (DIDANIN) (C - n/a - n/a - [n/a - n/a - n/a]), (DIPYRIBODOL) (C - n/a - n/a - [n/a - n/a - n/a]), (SMVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000571202	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a] - Intramuscular)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a] - Intramuscular)	ICSR
EU-EC-1000572025	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000572429	07/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000572432	07/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000572554	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	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 - n/a])	Not reported	ICSR
EU-EC-1000584980	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Acute coronary syndrome (03 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Death (03 - Fatal - Results in Death), Sudden death (03 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10005852397	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Sudden death (01 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CIRCADIN (MELTANIN) (C - n/a - Unknown - [n/a - n/a - n/a]), (AMLODIPINE, AMLODIPINE BESILATE) (C - n/a - Unknown - [n/a - n/a - n/a]), (COLICLAFEROL) (C - n/a - Unknown - [n/a - n/a - n/a]), (DIAZEPAM) (C - n/a - Unknown - [n/a - n/a - n/a]), (ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE) (C - n/a - Unknown - [n/a - n/a - n/a]), (EZETIMIBE) (C - n/a - Unknown - [n/a - n/a - n/a]), (FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE) (C - n/a - Unknown - [n/a - n/a - n/a]), (FOLIC ACID) (C - n/a - Unknown - [n/a - n/a - n/a]), (IRBESARTAN) (C - n/a - Unknown - [n/a - n/a - n/a]), (LORMETAZEPAM) (C - n/a - Unknown - [n/a - n/a - n/a]), (METFORMIN, METFORMIN HYDROCHLORIDE) (C - n/a - Unknown - [n/a - n/a - n/a]), (MOXONIDINE) (C - n/a - Unknown - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - Unknown - [n/a - n/a - n/a]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - Unknown - [n/a - n/a - n/a]), (SOTALOL, SOTALOL HYDROCHLORIDE) (C - n/a - Unknown - [n/a - n/a - n/a]), (TASULICIN HYDROCHLORIDE) (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10005853100	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	C-reactive protein increased (12d - Fatal - Results in Death), Death (12d - Fatal - Results in Death), Dyspnoea (12d - Fatal - Results in Death), General physical health deterioration (12d - Fatal - Results in Death), Oxygen saturation decreased (12d - Fatal - Results in Death), Pneumonia (12d - Fatal - Results in Death), Pyrexia (12d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000585434	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000585438	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000585453	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	ELIQUIS (APIXABAN) (C - n/a - n/a - [n/a - n/a - n/a]), (AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE) (C - n/a - n/a - [n/a - n/a - n/a]), (CANDESARTAN) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000585616	06/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Asthenia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Not Recovered/Not Resolved -), General physical health deterioration (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10005856296	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Cerebrovascular accident (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10005856790	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10005856718	05/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Feeling cold (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypohidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Insomnia (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005858048	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE (C - n/a - n/a -), (SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE) (C - Asthma - n/a -), (THEOPHYLLINE) (C - n/a - n/a -)	ICSR
EU-EC-10005858716	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005858798	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005854410	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10005854668	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - Ischaemic stroke - n/a - [n/a - 75mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a])	ICSR
EU-EC-100058547978	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	FLUOXETINE (C - n/a - n/a - [n/a - 15mg - Oral]), (AMLODIPINE, AMLODIPINE BESILATE) (C - Hypertension - n/a - [n/a - 10mg - Oral]), (BISACODYL) (C - Constipation - n/a - [n/a - 10mg - Oral]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - Diuretic therapy - n/a - [n/a - 20mg - Oral]), (MORPHINE HYDROCHLORIDE) (C - Pain - n/a - [n/a - 10mg - Oral]), (MORPHINE SULFATE) (C - Pain - n/a - [n/a - n/a - Oral]), (PARACETAMOL) (C - Pain - n/a - [n/a - 1000mg - Oral]), (POTASSIUM CHLORIDE) (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), (POTASSIUM, SODIUM, MAGNESIUM, 3550, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MAGNESIUM, 3550) (C - Constipation - n/a - [n/a - 1DF] - Oral), (VITAMIN D, CALCIUM) (C - Mineral supplementation - n/a - [n/a - 1DF] - Oral), (VITAMIN D) (C - Vitamin supplementation - n/a - [n/a - 1DF] - Oral)	ICSR
EU-EC-10005852351	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Myelodysplastic syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	AZACITIDINE (AZACITIDINE) (C - Myelodysplastic syndrome - n/a - [n/a - n/a - n/a]), POSACONAZOLE POSACONAZOLE (C - Myelodysplastic syndrome - n/a - [n/a - n/a - n/a]), (CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE) (C - n/a - n/a - [n/a - 10mg - n/a]), (ERYTHROPOLYMER) (C - Myelodysplastic syndrome - n/a - [n/a - 150mg - n/a]), (METOCLOPRAMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (OMEPRAZOLE) (C - Dyspepsia - n/a - [n/a - 10mg - n/a - More in ICSR]), (ONDANSETRON) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - 4g - n/a]), (SOLIFENACIN) (C - Hypertension - n/a - [n/a - 5mg - n/a]), (TRIMETHOPRIM) (C - Thrombocytopenia - n/a - [n/a - 1500mg - n/a])	ICSR
EU-EC-10005852448	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (03 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10005852538	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	Chest pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Injection site reaction (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(ACETYSALICYLIC ACID) (C - n/a - Unknown - [n/a - n/a - n/a]), (AESCULUS HIPPOCASTANUM L., AESCULUS HIPPOCASTANUM L. SEED DRY EXTRACT, DRY EXTRACT OF COMMON HORSE CHESTNUT, HORSE CHESTNUT DRY EXTRACT, HYDROALCOHOLIC) (C - n/a - Unknown - [n/a - n/a - n/a]), (AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL) (C - n/a - Unknown - [n/a - n/a - n/a]), (HYDROCHLOROTHIAZIDE, NEBIVOLOL) (C - n/a - Unknown - [n/a - n/a - n/a]), (DULOXETINE (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Anxiety - n/a - [n/a - 20mg - n/a]), (LUMIGAN (Bimatoprost) (C - Eye disorder - n/a - [n/a - n/a - n/a]), (ACETYSALICYLIC ACID) (C - Cardiac disorder - n/a - [n/a - 81mg - n/a]), (ASCORBIC ACID, CYANOCOBALAMIN, THIAMINE, IRON) (C - Renal disorder - n/a - [n/a - n/a - n/a]), (CARVEDILOL) (C - Hypertension - n/a - [n/a - 3.125mg - n/a]), (GLIMPERID) (C - Hypertension - n/a - [n/a - 1mg - n/a]), (DIAZEPAM, DIAZEPAM BESILATE) (C - Hypertension - n/a - [n/a - 4mg - n/a]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Hypertension - n/a - [n/a - 5mg - n/a]), (MIRTAZAPINE) (C - Anxiety - n/a - [n/a - 15mg - n/a]), (PARACETAMOL) (C - Pain - n/a - [n/a - 500mg - n/a]), (SMVASTATIN) (C - Cardiac disorder - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10005852640	04/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Aphonia (n/a - Unknown - Disabling), Death (n/a - Fatal - Results in Death), Dysarthria (n/a - Unknown - Disabling), Guillain-Barre syndrome (n/a - Unknown - Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Disabling), Muscular weakness (n/a - Unknown - Disabling)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	DULOXETINE (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Anxiety - n/a - [n/a - 20mg - n/a]), (LUMIGAN (Bimatoprost) (C - Eye disorder - n/a - [n/a - n/a - n/a]), (ACETYSALICYLIC ACID) (C - Cardiac disorder - n/a - [n/a - 81mg - n/a]), (ASCORBIC ACID, CYANOCOBALAMIN, THIAMINE, IRON) (C - Renal disorder - n/a - [n/a - n/a - n/a]), (CARVEDILOL) (C - Hypertension - n/a - [n/a - 3.125mg - n/a]), (GLIMPERID) (C - Hypertension - n/a - [n/a - 1mg - n/a]), (DIAZEPAM, DIAZEPAM BESILATE) (C - Hypertension - n/a - [n/a - 4mg - n/a]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Hypertension - n/a - [n/a - 5mg - n/a]), (MIRTAZAPINE) (C - Anxiety - n/a - [n/a - 15mg - n/a]), (PARACETAMOL) (C - Pain - n/a - [n/a - 500mg - n/a]), (SMVASTATIN) (C - Cardiac disorder - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10005852622	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005852648	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005852700	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005852973	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Condition aggravated (n/a - Not Recovered/Not Resolved -), Cyanosis (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	(DIGOXIN) (C - n/a - n/a - [n/a - n/a - n/a]), (ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (MELPERONE, MELPERONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (METOPROLOL, SUCCLINATE, METOPROLOL TARTRATE) (C - Hypertension - n/a - [n/a - n/a - n/a]), (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (PERINDOPRIL ARGININE) (C - Hypertension - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - Pain - n/a - [n/a - 500mg - n/a]), (PARAFEN, PARAFEN SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (ZOLPIDEM, ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10005853026	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005853048	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	COVID-19 (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])	Not reported	ICSR
EU-EC-10005851283	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10005853141	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - n/a - n/a])	TRESIBA (INSULIN DEGLUCED) (C - n/a - n/a -), (ACETYSALICYLIC ACID) (C - n/a - n/a -), (AMLODIPINE, AMLODIPINE BESILATE) (C - n/a - n/a -), (HYDROCHLOROTHIAZIDE, LISINAPRIL, HYDROCHLOROTHIAZIDE, LISINAPRIL ANHYDROUS, LISINAPRIL DIHYDRATE, HYDROCHLOROTHIAZIDE) (C - n/a - n/a -), (LEVOTHYRONINE, LEVOTHYRONINE SODIUM) (C - n/a - n/a -), (PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE) (C - n/a - n/a -), (ZINC) (C - n/a - n/a -)	ICSR
EU-EC-10005853206	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [1d - n/a - Intramuscular])	(BUPRENORPHINE) (C - Pain - n/a - [n/a - 1DF] - Cutaneous), (CARBOMER, CARBOMER 980) (C - Dry eye - n/a - [n/a - 30mg] - Ophthalmic), (LACTULOSE) (C - Constipation - n/a - [n/a - 20mL - Oral]), (PARACETAMOL) (C - Pain - n/a - [n/a - 1g - n/a]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - Restlessness - n/a - [n/a - 25mg - Oral]), (SODIUM PICOSULFATE) (C - Constipation - n/a - [n/a - 20DF] - Oral), (VITAMIN D) (C - n/a - n/a - [n/a - 40ug - n/a])	ICSR
EU-EC-10005853886	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Confusional state (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10005851784	03/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (BUCESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL, FUMARATE, BUDESONIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (MONTELUKAST SODIUM) (C - n/a - n/a - [n/a - 10mg - n/a]), (SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - Asthma - n/a - [n/a - n/a - n/a]), (SMVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]), (ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10005858026	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Agnesia (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 10mg - n/a]), ELIQUIS (APIXABAN) (C - Anesthetisation - n/a - [n/a - 10mg - Oral]), FENTANYL, FENTANYL, FENTANYL CITRATE) (C - Pain - n/a - [n/a - n/a - Topical])	ICSR
EU-EC-1000488004	30/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	Death (n/a - Fatal - Results in Death), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMER		

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Region	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chtr - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chtr - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100037854	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - 3mL - Intramuscular])	RIVAROXABAN (RIVAROXABAN) (C - n/a - n/a - [1a - n/a - n/a]), SLEODOSIN (SLEODOSIN) (C - n/a - n/a - [1a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - n/a - n/a - [1a - n/a - n/a]), ENALAPRIL, ENALAPRIL MALEATE (C - n/a - n/a - [1a - n/a - n/a]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - n/a - n/a - [1a - n/a - n/a]), NEBIVOLOL (C - n/a - n/a - [1a - n/a - n/a]), OMEPRAZOLE (C - n/a - n/a - [1a - n/a - n/a]), SMASSTATIN (C - n/a - n/a - [1a - n/a - n/a]), METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE (C - n/a - n/a - [1a - n/a - n/a]), LANSOPRAZOLE (C - n/a - n/a - [1a - n/a - n/a]), SULFAMETHOXAZOLE, TRIMETHOPRIM (C - n/a - n/a - [1a - n/a - n/a])	ICSR
EU-EC-100038130	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100038284	21/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - 1DF] - n/a)	ENTRESTO 24 MG/24 MG FILM-COATED TABLETS (VALSARTAN, SACUBITRIL) (C - Cardiology/pt - Not applicable - [1a - n/a - n/a]), LIXIANA 15 MG FILM-COATED TABLETS (EDOXABAN) (C - Atrial fibrillation - Not applicable - [1a - n/a - n/a]), NOT AVAILABLE (C - Atrial fibrillation, Cardiology/pt - Not applicable - [1a - n/a - n/a]), DIGOXIN (C - Atrial fibrillation - Not applicable - [1a - n/a - n/a]), EPLERENONE (C - Cardiology/pt - Not applicable - [1a - n/a - n/a]), FURUSEMIDE (C - n/a - Not applicable - [1a - n/a - n/a])	ICSR
EU-EC-100038737	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Female	Not Specified	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100038849	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100038846	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100039056	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100039413	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100039564	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dyspnea (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100039893	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [1a - n/a - Intramuscular])	ESOMEPRAZOLE, ESOMEPRAZOLE SODIUM (C - Dyspepsia - n/a - [1a - 40mg - Oral]), METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE (C - Hypertension - n/a - [1a - 100mg - Oral]), DOXAZOSIN (C - Essential disorder - n/a - [1a - 25mg - Oral])	ICSR
EU-EC-100039973	20/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100040376	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Blood potassium increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100043455	20/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dyspnea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	FINASTERIDE (C - n/a - n/a - [1a - 5mg - n/a]), GABAPENTIN (C - n/a - n/a - [1a - 400mg - n/a]), LISINAPRIL, LISINAPRIL DRYDRATE (C - n/a - n/a - [1a - 2.5mg - n/a]), MONTELUKAST, MONTELUKAST SODIUM (C - n/a - n/a - [1a - 10mg - n/a]), OMEPRAZOLE (C - n/a - n/a - [1a - 20mg - n/a]), OXYCODONE, OXYCODONE HYDROCHLORIDE (C - Pain - n/a - [1a - 20mg - n/a]), OXYCODONE, PARACETAMOL (C - Pain - n/a - [1a - n/a - n/a]), PREDNISONE (C - n/a - n/a - [1mg - n/a - More in ICSR]), TAMBUSOLIN, TAMBUSOLIN HYDROCHLORIDE (C - n/a - n/a - [1a - 4mg - n/a]), WARFARIN, WARFARIN SODIUM (C - n/a - n/a - [1a - 2.5mg - n/a - More in ICSR])	ICSR
EU-EC-100043451	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100043628	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic aneurysm (n/a - Unknown - Other Medically Important Condition), Bacterial sepsis (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown -), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -), Gastrointestinal infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown -), Malaise (n/a - Recovered/Resolved -), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown -), Off label use (n/a - Unknown -), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vasculitis (n/a - Unknown - Other Medically Important Condition), Viral sepsis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Hypertension - n/a - [1a - n/a - n/a]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Type 2 diabetes mellitus - n/a - [1a - n/a - n/a]), THYROXINE (C - Hypothyroidism - n/a - [1a - n/a - n/a])	ICSR
EU-EC-100043656	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Asthma (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1a - 1DF] - Intramuscular)	ACETYSALICYLIC ACID (C - n/a - Dose not changed - [1a - 100mg - n/a]), COLCALSIFEROL, CALCIUM (C - n/a - n/a - [1a - 1DF] - n/a), FURUSEMIDE, FURUSEMIDE SODIUM (C - n/a - n/a - [1a - 40mg - n/a]), METAMIZOLE SODIUM MONOHYDRATE (C - n/a - n/a - [1a - 300mg - n/a]), METOPROLOL SUCCINATE, METOPROLOL TARTRATE, METOPROLOL TARTRATE PH EUR (C - n/a - Dose not changed - [1a - 47.5mg - n/a]), PREDNISONE (C - n/a - n/a - [1DF] - n/a), RETINOL, RETINOL PALMITATE, DEHPATHENOL (C - n/a - Dose not changed - [1a - 300mg - n/a])	ICSR
EU-EC-100043630	18/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Abdominal distension (n/a - Unknown -), Cardiomegaly (n/a - Unknown -), Condition aggravated (n/a - Unknown -), Confusion (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Ocular hyperaemia (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Productive cough (n/a - Unknown -), Sepsis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ACETYSALICYLIC ACID (C - Myocardial ischaemia - n/a - [1a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Hypertension - n/a - [1a - n/a - n/a]), ATORVASTATIN (C - Myocardial ischaemia - n/a - [1a - n/a - n/a]), BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE (C - Myocardial ischaemia - n/a - [1a - n/a - n/a]), CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE (C - n/a - n/a - [1a - n/a - n/a]), DOXAZOSIN, DOXAZOSIN MESLATE (C - n/a - n/a - [1a - n/a - n/a]), DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE (C - Chronic obstructive pulmonary disease - n/a - [1a - n/a - n/a]), FINASTERIDE (C - n/a - n/a - [1a - n/a - n/a]), PRAPROFENOL BROMIDE (C - n/a - n/a - [1a - n/a - n/a]), LOSARTAN, LOSARTAN POTASSIUM (C - n/a - n/a - [1a - n/a - n/a]), NICORANDIL (C - n/a - n/a - [1a - n/a - n/a]), PARACETAMOL, CODEINE PHOSPHATE (C - n/a - n/a - [1a - n/a - n/a]), TAMBUSOLIN, TAMBUSOLIN HYDROCHLORIDE (C - Benign prostatic hypertrophy - n/a - [1a - n/a - n/a]), ZOPICLONE (C - n/a - n/a - [1a - n/a - n/a])	ICSR
EU-EC-100043630	18/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100043643	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100043674	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100043683	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100043692	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100043147	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100043320	16/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Asthma (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 1DF] - Intramuscular)	ACETYSALICYLIC ACID, D,L-LYSINE ACETYSALICYLATE, LYSINE ASPIRIN, LYSINE ACETYSALICYLIC ACID (C - n/a - n/a -), AMLODIPINE, AMLODIPINE BESILATE (C - n/a - n/a -), BISOPROLOL, FUMARATE (C - n/a - n/a -), ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRHYDRATE (C - n/a - n/a -), MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM CARBONATE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL 3350, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350, SODIUM SULPHATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, (C - n/a - n/a -), IRIMENDINE, RILMENDINE DIHYDROGEN PHOSPHATE (C - n/a - n/a -), ZOPICLONE (C - n/a - n/a -)	ICSR
EU-EC-100043397	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [1a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100043394	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100043325	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Feeling hot (n/a - Unknown -), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypoglycaemia (n/a - Unknown - Other Medically Important Condition), Rash macular (n/a - Unknown -), Throat tightness (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	ACETYSALICYLIC ACID (C - Cardiac disorder - n/a - [1a - 81mg - Oral]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRHYDRATE (C - Hyperlipidaemia - n/a - [1a - 20mg - Oral]), DONPEZIL, HYDROCHLORIDE (C - Dementia - n/a - [1a - 5mg - Oral]), GABAPENTIN (C - Depression - n/a - [1a - 300mg - n/a]), GABAPENTIN (C - Pain - n/a - [1a - 300mg - n/a]), LISINAPRIL, LISINAPRIL DRYDRATE (C - Hypertension - n/a - [1a - 10mg - Oral]), METOPROLOL, METOPROLOL TARTRATE (C - Hypertension - n/a - [1a - 50mg - Oral]), NAPROXEN SODIUM (C - Pain - n/a - [1a - 220mg - Oral]), OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - Gastroesophageal reflux disease - n/a - [1a - 40mg - Oral]), PARACETAMOL (C - Body temperature increased, Pain - n/a - [1a - 325mg - Oral]), QUETIAPINE, QUETIAPINE FUMARATE (C - Abnormal behaviour, Dementia - n/a - [1a - 250mg - Oral]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Pain - n/a - [1a - 100mg - n/a])	ICSR
EU-EC-100043385	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100043460	15/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Agitation (n/a - Unknown -), Coordination abnormal (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown -), Dyspnea (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown -), Hallucination (n/a - Unknown - Other Medically Important Condition), Hypoglycaemia (n/a - Unknown -), Insomnia (n/a - Unknown -), Intrusive thoughts (n/a - Unknown -), Malaise (n/a - Unknown -), Muscle twitching (n/a - Unknown -), Pallor (n/a - Unknown -), Psychomotor hyperactivity (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - Other Medically Important Condition), Tachyphrenia (n/a - Unknown -), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (29 - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - n/a - n/a])	AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - n/a - n/a - [1a - 10mg - Oral]), GLEMERIDE (C - Diabetes mellitus - n/a - [1a - n/a - n/a]), LISINAPRIL, LISINAPRIL DRYDRATE (C - n/a - n/a - [1a - 10mg - n/a]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Diabetes mellitus - n/a - [1a - 100mg - Oral])	ICSR
EU-EC-100043193	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Dyspnea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100043184	15/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100043169	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Cardiorespiratory arrest (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved -), Hemiparesis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic stroke (45 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [1a - n/a - n/a])	Not reported	ICSR
EU-EC-100043043	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [1a - 3mL - Intramuscular])	ACETYSALICYLIC ACID (C - n/a - n/a -), ALLOPURINOL (C - n/a - n/a -), ALPRAZOLAM (C - n/a - n/a -), AMLODIPINE, AMLODIPINE BESILATE (C - n/a - n/a -), AMLODIPINE, INDAPAMIDE, PERINDOPRIL ARGININE, INDAPAMIDE, AMLODIPINE BESILATE, PERINDOPRIL ARGININE (C - n/a - n/a -), FENOFIBRATE (C - n/a - n/a -), PRACAVATAM (C - n/a - n/a -), RIBICAVATAMIN, ROBUVASTATIN CALCIUM (C - n/a - n/a -), RIVAROXABAN, RIVAROXABAN HYDROCHLORIDE (C - n/a - n/a -)	ICSR
EU-EC-100043046	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1a - n/a - n/a])	Not reported	ICSR

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Area	Literature Reference	Patent Age Group (as per report)	Patent Sex	Patent Age Group	Patent Sex	Patent Age Group	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
											Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -)			
EU-EC-1000830275	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000830279	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000830282	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000830221	14/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	No	Death (n/a - Fatal - Results in Death, Life Threatening), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening), COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Delirium (n/a - Fatal - Results in Death), Feeding disorder (n/a - Fatal - Results in Death), Fluid intake reduced (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000830641	14/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Eating disorder (n/a - Unknown -), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - [1DF] - n/a])	NON SPECIFIED DRUG [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000830387	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspareunia (n/a - Unknown -), Eating disorder (n/a - Unknown -), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [MORPHINE SULFATE] (C - Dyspareunia, Pain - n/a - [n/a - 50mg - n/a]), [PARACETAMOL] (C - Pain, Temperature regulation disorder - n/a - [n/a - 650mg - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Sleep disorder - n/a - [n/a - 50mg - Oral])	ICSR
EU-EC-1000830916	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Not Resolved)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828928	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Asthma (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -), General physical health deterioration (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828912	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	No	COVID-19 (n/a - Unknown - Caused/Not Resolved, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Caused/Not Resolved, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000829070	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000829113	13/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Peripheral circulatory failure (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000829194	13/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Blood pressure fluctuation (n/a - Not Recovered/Not Resolved - Caused/Not Resolved), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Not Recovered/Not Resolved -), Dyspareunia (n/a - Recovered/Resolved - Caused/Not Resolved), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Not Resolved), Headache (n/a - Recovered/Resolved - Caused/Not Resolved), Stress (n/a - Unknown - Caused/Not Resolved), Intentional product use issue (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Not Resolved), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Not Resolved), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Not Resolved), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Not Resolved), Pulse abnormal (n/a - Not Recovered/Not Resolved - Caused/Not Resolved), Therapeutic product effect incomplete (n/a - Not Recovered/Not Resolved -), Vaccination complication (n/a - Unknown - Caused/Not Resolved)	FIRDAPSE [AMIFAMPRIIDINE] (S - Myasthenic syndrome - Dose not changed - [n/a - 10mg - Oral - More in ICSR]), FIRDAPSE [AMIFAMPRIIDINE] (S - Myasthenic syndrome - Unknown - [n/a - 30mg - Oral - More in ICSR]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ACETYL SALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), (FUROSEMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000829254	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - Unknown - [n/a - 1DF] - n/a), OXYBUTYRIN [OXYBUTYRIN, OXYBUTYRIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 10mg - n/a]), (ANHYDROUS LEVOTHYROXINE SODIUM) (C - n/a - Unknown - [n/a - 1DF] - n/a), (BISMETAMIDE) (C - n/a - Unknown - [n/a - 1DF] - n/a), (FOSFONON FOSFONON TROMETAMOL) (C - n/a - Unknown - [n/a - 1DF] - n/a), (LORAZEPAM) (C - n/a - Unknown - [n/a - 1DF] - n/a), (NEBIVOLOL) (C - n/a - Unknown - [n/a - 505] - n/a), (PASSIFLORA INCARNATA DRY EXTRACT) (C - n/a - Unknown - [n/a - 1DF] - n/a), (PMZOZIDE) (C - n/a - Unknown - [n/a - 2DF] - n/a)	ICSR
EU-EC-1000829650	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000827489	12/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	No	Asthma (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Gastrointestinal disorder (n/a - Recovered/Resolved -), Mabate (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000827617	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - Intramuscular])	(BUPRENORPHINE) (C - n/a - n/a -)	ICSR
EU-EC-1000827684	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - Intramuscular])	(BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - Hypertension - n/a - [n/a - 1.25mg - Oral - More in ICSR]), (BUPRENORPHINE) (C - Back pain - n/a - [n/a - n/a - Transdermal]), (CALCIOTRIM) (SALMON) (C - n/a - Unknown - [n/a - 1DF] - n/a), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - Hypertension - n/a - [800d - n/a - Oral]), (PARACETAMOL, PARACETAMOL, ASPARTAME) (C - Pain - n/a - [n/a - 1g - Oral]), (DIETAPINE) (C - n/a - n/a - [n/a - n/a - Oral]), (SODIUM PICOSULFATE) (C - n/a - n/a -)	ICSR
EU-EC-1000827864	12/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Apnoea (n/a - Unknown - Life Threatening), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Hypotension (n/a - Unknown - Life Threatening), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	FENTANYL [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a]), (INSULIN, INSULIN HUMAN) (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000827811	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000827927	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000827928	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828029	12/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	Not reported	ICSR
EU-EC-1000828038	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death), Incorrect route of product administration (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-1000828101	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Asthma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Gait inability (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000828434	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000828469	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	KEPPRA [LEVETIRACETAM] (C - n/a - n/a -)	ICSR
EU-EC-1000828003	08/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Cardiac arrest (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000828003	08/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000828086	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	COVID-19 (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening), Drug ineffective (n/a - Unknown - Life Threatening, Other Medically Important Condition), Mabate (n/a - Recovered/Resolved - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	OLANZAPINE [OLANZAPINE] (C - Behaviour disorder - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - Behaviour disorder - n/a - [n/a - n/a - n/a]), (CARBAMAZEPINE, CARBAMAZEPINE [PH. EUR.]) (C - Behaviour disorder - n/a - [n/a - n/a - n/a]), (CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE) (C - Depressed mood - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000828418	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828190	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	CELECOXIB [CELECOXIB] (C - Depression - n/a - [n/a - 10mg - Oral]), DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - COVID-19 treatment - n/a - [5d - 4mg - Oral]), (ASCORBIC ACID) (C - COVID-19 treatment, Supplementation therapy - n/a - [n/a - 1000g - Oral]), (CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE) (C - Depression - n/a - [n/a - 10mg - Oral]), (DIGOXIN) (C - Cardiac failure - n/a - [n/a - 250g - Oral]), (DONEPEZIL HYDROCHLORIDE) (C - Dementia - n/a - [n/a - 10mg - Oral]), (LORAZEPAM) (C - Anxiety, Restlessness - n/a - [1200mg - 5mg - n/a]), (MEMANTINE HYDROCHLORIDE) (C - Dementia - n/a - [n/a - 20mg - Oral]), (MORPHINE SULFATE) (C - Dyspareunia, Pain - n/a - [1255min - 25mL - Oral]), (PARACETAMOL) (C - Arthralgia - n/a - [n/a - 500mg - n/a]), (PARACETAMOL) (C - Arthritis - n/a - [n/a - 650mg - Oral])	ICSR
EU-EC-1000828539	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828540	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828541	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828545	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828548	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828550	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828551	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828554	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000828693	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunosuppression - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000821894	08/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	No	No	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000824247	08/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000821653	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Asthma (n/a - Unknown - Caused/Not Resolved), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Fall (n/a - Unknown - Caused/Not Resolved), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Kidney infection (n/a - Unknown - Caused/Not Resolved, Other Medically Important Condition), Skin laceration (n/a - Unknown - Caused/Not Resolved), Wheezing (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000821659	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	No	COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved, Other Medically Important Condition), Vaccination failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved, Other Medically Important Condition)	COMIRNATY COVID-19 IMMUNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunosuppression - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000821920	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	(ACETYL SALICYLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]), (ATORVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]), (ENALAPRIL, ENALAPRIL MALEATE) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (SERTRALINE, SERTRALINE HYDROCHLORIDE) (

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
									Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Respiratory rate increased (n/a - Unknown -), Restlessness (n/a - Unknown -), Susceptibility (n/a - Unknown -)			
EU-EC-100022654	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Intracranial bleeds (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]) BAMNESPRINE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100022664	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - n/a])	XEPLION (PALIFERDIONE PALMITATE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100022620	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]) NOVORAPID 100 EML OPLÖSNING VOOR INJECTIE IN FLACON (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100022674	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-100022690	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Phylloxybis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100022684	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Phylloxybis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100022601	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100022614	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	PRADAXA (DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE) (C - Cardiovascular accident prophylaxis - n/a - [n/a - 110mg - Oral]), (BUMENTANIDE) (C - Diuretic therapy - n/a - [n/a - 1mg - Oral]), (CYANOCOBALAMIN, HYDROXYCOBALAMIN) (C - Vitamin supplementation - n/a - [n/a - 1mg - Oral]), (FERROUS CHLORIDE TETRAHYDRATE, FERROUS ION) (C - n/a - n/a - [n/a - 1mg - Oral]), (PARACETAMOL, PARACETAMOL, ASPARTAME) (C - Pain - n/a - [n/a - 1g - Oral]), (POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - Constipation - n/a - [n/a - 1(DP) - Oral]), (QUETIAPINE) (C - Frontotemporal dementia - n/a - [n/a - 50mg - Oral]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - Dyspnoea - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-100021381	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Bedridden (21d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Hypopnea (21d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	(SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a - n/a -), (XARELTO [RIVAROXABAN]) (C - n/a - n/a -), (BUDESONIDE, BUDESONIDE, MICROSPHERE) (C - n/a - n/a -), (DONEPEZIL, HYDROCHLORIDE) (C - n/a - n/a -), (DRIED FERROUS SULFATE, FERROUS SULFATE) (C - n/a - n/a -), (FUROSEMIDE) (C - n/a - n/a -), (HYDROXYCOBALAMIN) (C - n/a - n/a -), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a -), (MIRTAZAPINE) (C - n/a - n/a -), (PARACETAMOL) (C - n/a - n/a -), (POTASSIUM CHLORIDE) (C - n/a - n/a -), (POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a -), (SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a -), (CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE) (C - n/a - n/a - [40/47d - 40mg - n/a]), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [50/26d - 0.5mg - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a - [25/86d - n/a - n/a])	ICSR
EU-EC-100019332	05/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thalamic infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), White matter lesion (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a -), (CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE) (C - n/a - n/a - [40/47d - 40mg - n/a]), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [50/26d - 0.5mg - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a - [25/86d - n/a - n/a])	ICSR
EU-EC-100019369	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Aspiration (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100019365	05/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	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])	Not reported	ICSR
EU-EC-100018479	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Blood countine increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	BRILIQUE (TICAGRELOR) (C - n/a - n/a - [n/a - 50mg - n/a]), (ATORVASTATIN) (C - n/a - n/a - [n/a - 40mg - n/a]), (LOSARTAN, LOSARTAN POTASSIUM) (C - n/a - n/a - [n/a - 50mg - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100019509	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(ATORVASTATIN) (C - Hypercholesterolemia - n/a - [n/a - n/a - n/a]), (COLECALCIFEROL, CALCIUM CARBONATE) (C - Osteopenia - n/a - [n/a - n/a - n/a]), (OMEPRAZOLE) (C - Dyspepsia - n/a - [n/a - n/a - n/a]), (SMIPRIS) (C - Hypertension - n/a - [n/a - n/a - n/a]), (VANCOMYCIN, VANCOMYCIN HYDROCHLORIDE) (C - C-reactive protein increased - n/a - [43d - n/a - n/a])	ICSR
EU-EC-100018989	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Chills (n/a - Not Recovered/Not Resolved - Life Threatening), Communication disorder (n/a - Unknown - Life Threatening), Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown - Life Threatening), Inappropriate schedule of product administration (n/a - Unknown -), Malaise (n/a - Unknown - Life Threatening), Oral labor use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a -), (CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE) (C - n/a - n/a - [40/47d - 40mg - n/a]), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [50/26d - 0.5mg - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a - [25/86d - n/a - n/a])	ICSR
EU-EC-100018205	04/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	(ROSVUASTATIN, ROSUVASTATIN CALCIUM) (C - Dyslipaemia - n/a - [n/a - 1(DP) - Oral])	ICSR
EU-EC-100017942	03/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-100017604	03/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-100017619	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-100017161	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Oxygen saturation decreased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000181740	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100018443	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100018454	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	(AMLODIPINE) (C - n/a - n/a - [n/a - 10mg - n/a]), (ATROLOL) (C - n/a - n/a - [n/a - 50mg - n/a]), (BESONATADINE) (C - n/a - n/a - [n/a - 5mg - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - 1000mg - n/a]), (ZINCLOX) (C - n/a - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-100018387	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Arrhythmia (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Recovered/Resolved -), Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Malaise (n/a - Unknown -), Tachypnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - n/a])	AUSKREN 300MG TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100018384	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100018692	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]), (ALLOPURINOL) (C - n/a - n/a - [n/a - 100mg - n/a]), (ATORVASTATIN) (C - n/a - n/a - [n/a - 40mg - n/a]), (BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE) (C - n/a - n/a - [n/a - 1(DP) - n/a]), (COLECALCIFEROL) (C - n/a - n/a - [n/a - 800U - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - 40mg - n/a]), (OMEPRAZOLE) (C - n/a - n/a - [n/a - 20mg - n/a]), (TIOTROPUM, TIOTROPUM BROMIDE MONOHYDRATE) (C - n/a - n/a - [n/a - 18ug - n/a])	ICSR
EU-EC-1000187199	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100018480	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000185133	31/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiovascular accident (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), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Peripheral swelling (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000184577	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	(ACETYLSALICYLIC ACID) (C - n/a - n/a - [n/a - 100mg - n/a]), (AMLODIPINE BESILATE, PERINDOPRIL ARGININE) (C - n/a - n/a - [n/a - n/a - n/a]), (CLOPIDOGREL) (C - n/a - n/a - [n/a - 75mg - n/a]), (COLECALCIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]), (DONEPEZIL, HYDROCHLORIDE) (C - n/a - n/a - [n/a - 10mg - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - 40mg - n/a]), (MEMANTINE, HYDROCHLORIDE) (C - n/a - n/a - [n/a - 20mg - n/a]), (METAMIZOLE, MAGNESIUM, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE) (C - n/a - n/a - [n/a - 500mg - n/a]), (METOPROLOL, TRINTRATE) (C - n/a - n/a - [n/a - 50mg - n/a]), (TRAZODONE, HYDROCHLORIDE) (C - n/a - n/a - [n/a - 300mg - n/a]), (PREGABALIN MYLAN 150 MG HARD CAPSULES [PREGABALIN]) (C - n/a - n/a - [n/a - n/a - n/a]), (VFEND 200 MG FILM-COATED TABLETS [VORICONAZOLE]) (C - n/a - n/a - [n/a - n/a - n/a]), (ALPRAZOLAM) (C - n/a - n/a - [n/a - n/a - n/a]), (AMODARONE, HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (ATOVAGUONE) (C - n/a - n/a - [n/a - n/a - n/a]), (BACLOFEN) (C - n/a - n/a - [n/a - n/a - n/a]), (BISOPROLOL, HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]), (MORPHINE SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (TINZAPARIN, TINZAPARIN SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (VALACICLOVIR) (C - n/a - n/a - [n/a - n/a - n/a]), (ZINCLOX) (C - n/a - n/a - [n/a - n/a - n/a]), (CITALOPRAM, CITALOPRAM HYDROBROMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (ENALAPRIL, MALEATE) (C - n/a - n/a - [n/a - n/a - n/a]), (EPINEPHRINE) (C - n/a - n/a - [n/a - n/a - n/a]), (GABAPENTIN) (C - n/a - n/a - [n/a - n/a - n/a]), (LACTULOSE, LACTULOSE, LIQUID) (C - n/a - n/a - [n/a - n/a - n/a]), (MIRTAZAPINE) (C - n/a - n/a - [n/a - n/a - n/a]), (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]), (PROPRANOLOL, PROPRANOLOL, HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000184938	31/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical condition abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000185204	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Myocardial ischaemia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	PRADAXA (DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE) (C - Anticoagulant therapy - n/a - [182d - n/a - n/a]), TYNISTA 40 MG/50 MG TABLETS (AMLODIPINE, TELMISARTAN) (C - Blood pressure management - n/a - [182d - n/a - n/a]), UROREX (SODIUM) (C - Benign prostatic hypertrophy - n/a - [182d - n/a - n/a]), (BISOPROLOL, FUMARATE) (C - Hypertension - n/a - [182d - n/a - n/a]), (COLECALCIFEROL) (C - Vitamin D deficiency - n/a - [182d - n/a - n/a]), (DONEPEZIL) (C - Dementia Alzheimer's type - n/a - [182d - n/a - n/a]), (ESITALOPRAM, ESCITALOPRAM OXALATE) (C - Depression - n/a - [182d - n/a - n/a]), (FUROSEMIDE) (C - Diuretic therapy - n/a - [177d - n/a - n/a]), (LACTULOSE) (C - Constipation - n/a - [86d - n/a - n/a]), (MEMANTINE) (C - Dementia Alzheimer's type - n/a - [181d - n/a - n/a]), (MIRTAZAPINE) (C - Major depression - n/a - [182d - n/a - n/a]), (QUETIAPINE) (C - Depression - n/a - [182d - n/a - n/a]), (ROSVUASTATIN, ROSUVASTATIN CALCIUM) (C - Lipids abnormal - n/a - [182d - n/a - n/a]), (TRAZODONE, HYDROCHLORIDE) (C - Depression - n/a - [145d - n/a - n/a]), (ALICOPRINIL) (C - n/a - n/a - [n/a - 300mg - n/a]), (BISOPROLOL, FUMARATE) (C - n/a - n/a - [n/a - 5mg - n/a]), (ENALAPRIL, MALEATE) (C - n/a - n/a - [n/a - 5mg - n/a]), (FUROSEMIDE) (C - n/a - n/a - [n/a - 80mg - n/a]), (GLYCERYL TRINTRATE) (C - n/a - n/a - [n/a - 4mg - n/a]), (ISOSORBIDE MONONITRATE) (C - n/a - n/a - [n/a - 30mg - n/a]), (NITROFURANTOIN) (C - n/a - n/a - [n/a - 50mg - n/a]), (OMEPRAZOLE) (C - n/a - n/a - [n/a - 20mg - n/a]), (OXAZEPAM) (C - n/a - n/a - [n/a - 5mg - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - 1000mg - n/a]), (UREA) (C - n/a - n/a - [n/a - n/a - n/a]), (WARFARIN SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (ZINCLOX) (C - n/a - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-1000185107	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	(ROSVUASTATIN, ROSUVASTATIN CALCIUM) (C - Lipids abnormal - n/a - [182d - n/a - n/a]), (TRAZODONE, HYDROCHLORIDE) (C - Depression - n/a - [145d - n/a - n/a]), (ALICOPRINIL) (C - n/a - n/a - [n/a - 300mg - n/a]), (BISOPROLOL, FUMARATE) (C - n/a - n/a - [n/a - 5mg - n/a]), (ENALAPRIL, MALEATE) (C - n/a - n/a - [n/a - 5mg - n/a]), (FUROSEMIDE) (C - n/a - n/a - [n/a - 80mg - n/a]), (GLYCERYL TRINTRATE) (C - n/a - n/a - [n/a - 4mg - n/a]), (ISOSORBIDE MONONITRATE) (C - n/a - n/a - [n/a - 30mg - n/a]), (NITROFURANTOIN) (C - n/a - n/a - [n/a - 50mg - n/a]), (OMEPRAZOLE) (C - n/a - n/a - [n/a - 20mg - n/a]), (OXAZEPAM) (C - n/a - n/a - [n/a - 5mg - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - 1000mg - n/a]), (UREA) (C - n/a - n/a - [n/a - n/a - n/a]), (WARFARIN SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (ZINCLOX) (C - n/a - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-1000185202	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU Local Number	EY Category	Report Type	Primary Source	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chx - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Chx - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-1000807046	25/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Not Recovered/Not Resolved -)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	POTASSIUM CHLORIDE (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), [RAMIPRIL (C - Hypertension - n/a - [n/a - 5mg - Oral]), TERBUTALINE SULFATE (C - Chronic obstructive pulmonary disease - n/a - [n/a - 5mg - Respiratory (inhalation)), [DIPROPIONYL MELATONIN (C - Chronic obstructive pulmonary disease - n/a - [n/a - 2(DP) - Respiratory (inhalation))], MELATONIN (MELATONIN) (C - n/a - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - n/a - n/a - [n/a - n/a - n/a]), [CAN, TAR SOLUTION BY PRECIPITATED SULFUR BP, SALICYLIC ACID PH. EUR., COAL TAR SOLUTION, SALICYLIC ACID, SULFUR] (C - n/a - n/a - [n/a - n/a - n/a]), [COCOSUREL] (C - n/a - n/a - [n/a - 750g - n/a]), [FLUDOXETINE, FLUDOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [RAMIPRIL (C - n/a - n/a - [n/a - n/a - n/a]), [SALSALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000807416	25/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Haematomas (n/a - Unknown -), Road traffic accident (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(DP) - n/a])	Not reported	ICSR
EU-EC-1000803096	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000805406	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000805472	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000805638	24/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abdominal infection (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Urinary tract infection (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL, TERBUTALINE] (C - n/a - n/a - [n/a - n/a - n/a]), [LIXIANA (EDOXABAN, EDOXABAN TOSYLATE)] (C - n/a - n/a - [n/a - n/a - n/a]), [CODEINE] (C - Cough - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PIPAMPERONE, PIPAMPERONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000805628	24/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000803209	24/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Chills (n/a - Unknown -), Hypotonia (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000803213	24/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Hypophagia (n/a - Not Recovered/Not Resolved -), Hypotonia (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000803411	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000803606	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Circulatory collapse (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000803137	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (S) - Fatal - Results in Death, CausedProlonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (S) - Fatal - Results in Death, CausedProlonged Hospitalisation), Drug ineffective (S) - Fatal - Results in Death, CausedProlonged Hospitalisation), Inability (S) - Fatal - Results in Death, CausedProlonged Hospitalisation), Malaise (15d - Fatal - Results in Death, CausedProlonged Hospitalisation), Pain (S) - Fatal - Results in Death, CausedProlonged Hospitalisation), Pneumonia (12d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008041320	23/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Cardiac arrest (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - CausedProlonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008041893	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008042141	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008043066	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(DP) - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LIDOCAINE, LIDOCAINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008043213	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10008043551	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10008044966	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - Not applicable - [n/a - 1(DP) - Oral]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [CIRCADIN (MELATONIN)] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER, CARBOMER 974P] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL, MALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM BIPHENOLATE, SODIUM BIPHENOLATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL, TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIMOLOL, TIMOLOL, MALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISACODYL, DOCCULATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - Constipation - n/a - [n/a - 10mg - Rectal]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1(DP) - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 2000IU - n/a]), [DOCCULATE SODIUM, SENNOSIDE A/B] (C - Constipation - n/a - [n/a - 500mg - Oral]), [ERYTHROMYCIN] (C - n/a - n/a - [n/a - 5g - Ophthalmic]), [ESTRADIOL] (C - n/a - n/a - [n/a - 5g - Vaginal]), [HALOPERIDOL, HALOPERIDOL, DECANOATE] (C - n/a - n/a - [n/a - 25mL - Oral]), [HYDROCORTISONE ACETATE, PERU BALSAM, ZINC OXIDE, BENZYL BENZOATE, BISMUTH OXIDE, BISMUTH SUBGALLATE, HYDROCORTISONE ACETATE, ZINC SULFATE] (C - Proctitis - n/a - [n/a - n/a - Rectal]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - 8DP] - Oral), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral - More in KSR]), [SENA ALEXANDRINA LEAF, CASSIA] (C - n/a - n/a - [n/a - 8.6mg - Oral]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008046562	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008048005	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diet refusal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musian (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sedation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - Not applicable - [n/a - 1(DP) - Oral]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [CIRCADIN (MELATONIN)] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER, CARBOMER 974P] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL, MALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM BIPHENOLATE, SODIUM BIPHENOLATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL, TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIMOLOL, TIMOLOL, MALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISACODYL, DOCCULATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - Constipation - n/a - [n/a - 10mg - Rectal]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1(DP) - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 2000IU - n/a]), [DOCCULATE SODIUM, SENNOSIDE A/B] (C - Constipation - n/a - [n/a - 500mg - Oral]), [ERYTHROMYCIN] (C - n/a - n/a - [n/a - 5g - Ophthalmic]), [ESTRADIOL] (C - n/a - n/a - [n/a - 5g - Vaginal]), [HALOPERIDOL, HALOPERIDOL, DECANOATE] (C - n/a - n/a - [n/a - 25mL - Oral]), [HYDROCORTISONE ACETATE, PERU BALSAM, ZINC OXIDE, BENZYL BENZOATE, BISMUTH OXIDE, BISMUTH SUBGALLATE, HYDROCORTISONE ACETATE, ZINC SULFATE] (C - Proctitis - n/a - [n/a - n/a - Rectal]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - 8DP] - Oral), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral - More in KSR]), [SENA ALEXANDRINA LEAF, CASSIA] (C - n/a - n/a - [n/a - 8.6mg - Oral]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008050248	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Disease recurrence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000805104	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Malaise (n/a - Unknown -), Myocardial infarction (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVEMIR (INSULIN DETEMIR)] (C - n/a - n/a - [n/a - n/a - n/a]), [NOVOPRIN (INSULIN ASPART)] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008026028	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000802664	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000802665	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aphasia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008027099	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008028593	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008029366	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Chest pain (20min - Recovered/Resolved - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death), Hypertension (20min - Recovered/Resolved - CausedProlonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - n/a])	[APIXABAN 5MG TABLET] (C - n/a - n/a - [n/a - n/a - n/a]), [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008020028	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000790653	18/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10007901913	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[RELVAR ELLIPTA (FLUTICASON FURATE, VILANTEROL)] (C - Chronic obstructive pulmonary disease - n/a - n/a - [n/a - 1(DP) - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMOXICILIN, AMOXICILIN HYDROCHLORIDE] (C - Atrial fibrillation - n/a - [n/a - 200mg - n/a]), [BISACODYL] (C - Constipation - n/a - [n/a - n/a - n/a]), [BURMETANDE] (C - Cardiac failure - n/a - [n/a - 1mg - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 2000IU] - n/a]), [CYANOCOBALAMIN, HYDROCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - n/a]), [ENOXAPRIN SODIUM] (C - Thrombosis prophylaxis - n/a -), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE, LIQUID] (C - Constipation - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE] (C - Osteoarthritis - n/a - [n/a - 10mg - Oral]), [OXAZEPAM] (C - Insomnia - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - Osteoarthritis, Pain - n/a -), [POTASSIUM CITRATE] (C - Hypokalaemia - n/a - [n/a - 600mg - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1(DP) - n/a]), [SALBUTAMOL, SALBUTAMOL, SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - Cardiac failure - n/a - [n/a - 25mg - n/a]), [DOPICOLIN]	

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Purpose	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Ch# - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Ch# - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
										Pyrexia (n/a - Fatal - Results in Death)		[ALLOPURINOL] (C - n/a - Not applicable - [n/a - 100mg - Oral]), [AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - Not applicable - [n/a - 25mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Not applicable - [n/a - 5mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - Not applicable - [n/a - n/a - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Not applicable - [n/a - 10mg - Oral]), [CLONAZEPAM] (C - n/a - Not applicable - [n/a - n/a - Oral]), [DIAZEPAM] (C - n/a - Not applicable - [n/a - 5mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - n/a - Not applicable - [n/a - 500mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Not applicable - [n/a - 40mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Not applicable - [n/a - n/a - Oral]), [PARACETAMOL, TRAMADOL, TRAMADOL HYDROCHLORIDE, PARACETAMOL] (C - n/a - Not applicable - [n/a - 10DF - Oral]), [DOLIPREN TARTRATE] (C - n/a - Not applicable - [n/a - 5mg - Oral]), [NON SPECIFIED STATINE (NOT AVAILABLE)] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [XARELTO 15 MG (RIVAROXABAN)] (C - n/a - Does not changed -)	ICSR
EU-EC-1000800575	18/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)		ICSR
EU-EC-1000800584	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)		ICSR
EU-EC-1000800374	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Gastroenteritis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - n/a)	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 10DF - n/a]), [DRY EXTRACT OF GINKGO BILBA LEAVES (G647-1), EXTRACTION SOLVENT: ACETONE 60% (M/N), GINKGO BILBA] (C - n/a - Does not changed - [n/a - 100mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 3DF] - n/a), [TRIAZOLAM] (C - n/a - n/a - n/a -)	ICSR
EU-EC-1000797484	18/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000797491	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000797400	18/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin discoloration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000797717	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000795947	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular)	Not reported	ICSR
EU-EC-1000795822	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000795995	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007960749	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000796080	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Face oedema (n/a - Unknown - Results in Death), Hypertension (n/a - Unknown - Results in Death), Oedema peripheral (n/a - Unknown - Results in Death), Pyrexia (n/a - Unknown - Results in Death), Tachycardia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000796083	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000796270	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertensive crisis (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Tumor (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Vertigo (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Visual impairment (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000796467	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000794704	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000794879	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000794927	16/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Confusion (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Personality change (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007931687	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Bleat infected (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007931817	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ALENDRONATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, BUDESONIDE MICRONISED] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007931821	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007931861	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[BETMIG (MRABEGRON)] (C - n/a - n/a - [n/a - n/a - n/a]), [ASORBIC ACID, SUCCINIC ACID, IRON, FERROUS (II) GLYCINE SULFATE COMPLEX, FERROUS (II) GLYCINE SULFATE COMPLEX, POLYSACCHARIDE IRON COMPLEX] (C - n/a - n/a - [n/a - n/a - n/a]), [FURUSEMIDE, FURUSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [FURUSEMIDE, FURUSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MOPHINE, MOPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007932284	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007932753	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007924179	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death), General physical condition abnormal (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007934867	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - 200mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 30mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 80mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 10DF - n/a])	ICSR
EU-EC-10007934900	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	[CALCIUM POLYSTYRENE SULFONATE] (C - n/a - n/a - [n/a - 1DF] - n/a), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), RIVAROXABAN 15MG TABLET (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007901674	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Diet refusal (8d - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007901790	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	Death (n/a - Fatal - Results in Death), Syncope (8d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007902877	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007906099	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AVAMYS (FLUTICASON FURATE)] (C - n/a - n/a - [n/a - n/a - n/a]), [BETMIG (MRABEGRON)] (C - n/a - n/a - [n/a - n/a - n/a]), COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (C - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), [PRIVIGEN (HUMAN NORMAL IMMUNOGLOBULIN)] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [FURUSEMIDE, FURUSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOMEPROLOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM OXIDE, MAGNESIUM OXIDE LIGHT] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007908757	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthena (n/a - Unknown -), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Discomfort (n/a - Unknown -), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Feeling cold (n/a - Unknown -), Hypothermia (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007908182	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007988371	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007988638	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007988672	11/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[KEPPRA (LEVITRACETAM)] (C - Seizure - n/a - [n/a - 10mL - Oral]), [LANTUS (INSULIN GLARGINE)] (C - Diabetes mellitus - n/a - [n/a - 10U]; Subcutaneous), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hyperlipidaemia - n/a - [n/a - 40mg - Oral]), [CASSIA] (C - Constipation - n/a - [n/a - 17.2mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 5000IU] - Oral), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 40mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 1000mg - Oral]), [PARACETAMOL, SUCCINATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 325mg - Oral])	ICSR
EU-EC-10007981400	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Coma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypertrophia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007981990	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007982484	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [FURUSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYALURONATE, SODIUM HYALURONATE, CARBOMER 981] (C - n/a - n/a - [n/a - n/a - n/a]), [GOSERELIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007984399	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESLATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DICYCLODOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007984973	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007985796	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Lung infiltration (n/a - Unknown -), Pneumonia (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FLAVIX (CLOPRODOL, CLOPRODOL HYDROGEN SULFATE)] (C - Anorexia - n/a - [n/a - 75mg - Oral]), [ACETYLSALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]), [AMLODIPINE BESILATE] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 1000IU] - Oral), [DIPNEPEZIL HYDROCHLORIDE] (C - Demersia - n/a - [n/a - 15mg - Oral]), [FOLIC ACID] (C - Supplementation therapy - n/a - [n/a - 1mg - Oral]), [FURUSEMIDE] (C - Oedema - n/a - [n	

EU Local Number	EY Category Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Purpose	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/NEZ Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000794237	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	[PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 650mg - Oral]), [POTASSIUM CHLORIDE] (C - Supplementation therapy - n/a - [n/a - 10g - Oral]), [PRIMEZONE] (C - Epilepsy - n/a - [n/a - 50mg - Oral])	ICSR
EU-EC-1000794843	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	[ESCALOPRAM, ESCALOPRAM OXALATE] (C - n/a - Drug withdrawn - [n/a - 10(mg) - Oral]), [LOXAPINE] (C - n/a - Drug withdrawn - [n/a - 15(mg) - Oral]), [OXAZEPAM] (C - n/a - Drug withdrawn - [n/a - 5(mg) - Oral]), [PARACETAMOL] (C - n/a - Does not changed - [n/a - 1(Df) - Oral])	ICSR
EU-EC-1000795182	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000795442	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), General physical condition abnormal (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000797723	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-1000798357	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death), Mucosa (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	HYDROXOCOBALAMIN (HYDROXOCOBALAMIN) (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOPOL, LEVOCOPOL, LEVOCOPOL MONOHYDRATE] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [GANTEROL 0.3 MG/MG + SGLM, [TMOLOL, MILEPATE, BMATOPROST]] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000798436	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-1000798220	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30g - Intramuscular])	Not reported	ICSR
EU-EC-1000798227	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30g - Intramuscular])	Not reported	ICSR
EU-EC-1000798473	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death), Dyspepsia (n/a - Not Recovered/Not Resolved - Results in Death), Feeling hot (n/a - Not Recovered/Not Resolved - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	APIXABAN (APIXABAN) (C - n/a - n/a - [n/a - n/a - Oral]), LEVETIRACETAM (LEVETIRACETAM) (C - n/a - n/a - [n/a - n/a - Oral]), LUMIGAN (Bimatoprost) (C - n/a - n/a - [n/a - n/a - Ophthalmic]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - n/a - n/a - [n/a - n/a - Oral]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [CARTEOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [BERKANDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [MAGDROL 4000] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-1000798514	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000798824	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a -), [CARVEDILOL] (C - n/a - n/a -), [SPRINOLACTONE] (C - n/a - n/a -)	ICSR
EU-EC-1000794706	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000794807	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000794934	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007949163	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007949421	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - Oral]), [DOPLOLONE] (C - n/a - n/a - [n/a - n/a - Oral]), [EUFORGE (VALSARTAN, ALMOLOPINE, VALSARTAN, ALMOLOPINE BESILATE)] (C - n/a - n/a - [n/a - n/a - n/a]), ZYREXA 10 MG COATED TABLET (DOLAZAPINE) (C - n/a - n/a - [n/a - 10mg - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [QUETIAPINE] (C - n/a - n/a - [n/a - 100mg - n/a])	ICSR
EU-EC-1000794987	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Chest pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -), Oedema peripheral (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007950196	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007950200	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950211	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950212	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), General physical health deteriorated (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950213	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950219	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Respiratory distress (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950221	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Respiratory distress (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950222	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Gait instability (n/a - Not Recovered/Not Resolved -), Quadriceps (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950224	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death), Asthma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007950226	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Asthma (n/a - Unknown -), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Lethargy (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950227	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Dehydration (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Gastrointestinal pain (n/a - Unknown -), Nausea (n/a - Unknown -), Oliguria (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950228	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950231	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950235	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007950243	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), COVID-19 (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950244	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950245	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10007950255	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950256	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950259	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	Death (n/a - Fatal - Results in Death), COVID-19 (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007950261	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dementia (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 - Intramuscular])	Not reported	ICSR
EU-EC-10007950264	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950271	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007950273	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007950279	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007953156	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	[IRRESARTAN 150 MG - TABLET] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PAMPERONE] (C - n/a - n/a - [n/a - n/a - n/a]), [BUMETANIDE (BUMETANIDE)] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AZITHROMYCLIN, AZITHROMYCLIN DIHYDRATE, AZITHROMYCLIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENTRESTO 97 MG/100 MG FILM-COATED TABLETS (VALSARTAN, SACUBITRIL)] (C - n/a - n/a - [n/a - n/a - n/a]), [JANUVIA 50 MG FILM-COATED TABLETS (SITAGLIPTIN)] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007953867	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Muscle weakness (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AZITHROMYCLIN, AZITHROMYCLIN DIHYDRATE, AZITHROMYCLIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENTRESTO 97 MG/100 MG FILM-COATED TABLETS (VALSARTAN, SACUBITRIL)] (C - n/a - n/a - [n/a - n/a - n/a]), [JANUVIA 50 MG FILM-COATED TABLETS (SITAGLIPTIN)] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007953884	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Injection site pain (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10007957293	09/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death), Blue toe syndrome (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown -), Feeling hot (n/a - Unknown -), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown -), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved -), Skin discoloration (n/a - Unknown -), Tumor (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007952146	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [TOZINAMERAN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007952948	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLCALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000793008	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AZITHROMYCLIN, AZITHROMYCLIN DIHYDRATE, AZITHROMYCLIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [IPRATROPIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL	

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Economic Area	Literature Reference	Patient Age Group (as per report)	Patent Status	Patent Country	Patent Expiry	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
										Immunodeficiency (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown -), Pyrexia (n/a - Unknown -)			
EU-EC-1000779450	04/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a - More in ICSR])	Not reported	ICSR
EU-EC-1000774422	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000777706	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000777739	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000777784	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	DIEMANTINE (C - n/a - n/a - [n/a - n/a - n/a]), MIRTAZAPINE (C - n/a - n/a - [n/a - n/a - n/a]), RISPERIDONE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000778163	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778253	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000778217	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Caused/Not Resolved/Results in Death), Condition aggravated (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Illness (n/a - Unknown -), Malaise (n/a - Unknown -), Central nervous system (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778404	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778414	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal wall haematoma (n/a - Not Recovered/Not Resolved - Caused/Not Resolved/Results in Death), Abdominal wall haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Not Resolved/Results in Death, Other Medically Important Condition), Acute respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Not Resolved/Results in Death, Other Medically Important Condition), COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - Caused/Not Resolved/Results in Death), Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Not Resolved/Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000778506	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778579	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778669	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLORIDROREL (CLORIDROREL, CLORIDROREL BESILATE) (C - n/a - n/a - [n/a - n/a - n/a]), INSULIN ASPART (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a]), ALENDRONATE SODIUM, ALENDRONIC ACID (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLICALEFERRON, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCUSATE] (C - n/a - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a]), [LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000778924	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000778939	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000779251	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	KEPPRA (LEVETIRACETAM) (C - Epilepsy - n/a - [n/a - 2.5mL - n/a]), TOULED SOLOSTAR (INSULIN GLARGINE) (C - Diabetes mellitus - n/a - [n/a - 14U] - n/a), [CHLORZOXAZONE] (C - Muscle relaxant therapy - n/a - [n/a - 250mg - n/a]), [CLORIDROREL] (C - Thrombosis prophylaxis - n/a - [n/a - 75mg - n/a]), [FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - [n/a - 12ug - n/a]), [GLYCOPYRROLIUM BROMIDE, GLYCOPYRROLIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - Airway secretion clearance therapy - n/a - [n/a - 1mL - n/a]), [LANOPRAZOLE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [n/a - 30mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Metabolic disorder - n/a - [n/a - 50ug - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 1DF] - n/a), [MIRTAZAPINE] (C - Depression - n/a - [n/a - 15mg - n/a]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 10mL - n/a])	ICSR
EU-EC-1000778486	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Abdominal pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000778854	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Bacterial test positive (n/a - Fatal - Results in Death), Blood glucose increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Muscle twitching (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyelonephritis (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000778939	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), SARS-CoV-2 test negative (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000779406	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000778539	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a]), [NCOXIFAMIDE, RISOFOLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, RISOFOLAVIN SODIUM PHOSPHATE, THIAMINE HYDROCHLORIDE, NCOXIFAMIDE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1DF] - n/a), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TROTROPILUM, OLODATEROL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000773848	27/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000773912	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000774036	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000774028	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	[CARRIZAZOLE] (C - n/a - n/a - [n/a - 5mg - Oral]), [NADOLIL] (C - n/a - n/a - [n/a - 40mg - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - Oral])	ICSR
EU-EC-1000774027	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000774167	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hypotension (n/a - Not Recovered/Not Resolved - Results in Death), Malaise (n/a - Recovered/Resolved - Results in Death), Tachycardia (n/a - Unknown - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000774249	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Hypertension (1d - Recovered/Resolved - Results in Death), Hyperthermia (n/a - Not Recovered/Not Resolved - Results in Death), Lung disorder (n/a - Not Recovered/Not Resolved - Results in Death), Vaccination site inflammation (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000774270	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000772975	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	XARELTO 2.5 MG FILM-COATED TABLETS (RIVAROXABAN) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000772985	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000773003	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Chills (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Confusional state (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Fall (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Headache (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Hypophagia (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Hypotension (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Hypothermia (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Hypoxia (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Malaise (n/a - Unknown -), Oedema peripheral (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Skin ulcer (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Somnolence (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Tachypnoea (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Not Resolved/Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BRINZOLAMIDE (BRINZOLAMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID, ASPIRIN] (C - n/a - n/a - [n/a - 75mg - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000773206	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000773139	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID, ASPIRIN] (C - n/a - n/a - [n/a - 75mg - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000771978	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000772021	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Back pain (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Hypertension (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS (APIXIBAN) (C - Pulmonary embolism - n/a - [n/a - 5mg - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a -), [METOPROLOL, METOPROLOL HYDROCHLORIDE] (C - n/a - n/a -), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [OXAZEPAM] (C - n/a - n/a -), [PARACETAMOL, PARACETAMOL ASPARTAME] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-1000772096	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000772014	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000772119	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS (APIXIBAN) (C - Cerebral failure - n/a - [n/a - 2.5mg - Oral]), [ACETYLSALICYLIC ACID] (C - Myocardial infarction - n/a - [n/a - 75mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Cardiac failure - n/a - [n/a - 40mg - Oral]), [METFORMIN, METFORMAN HYDROCHLORIDE, METFORMAN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 500mg - n/a]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 50mg - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 750mg - Oral]), [RAMIPRIL] (C - Cardiac failure - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-1000772208	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000772214	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000772257	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000772249	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000772344	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000772354	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a	

EU Case Number	EY Category	Report Type	Primary Source	Primary Country	Literature Reference	Patient Age Group (at report)	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chg - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chg - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100070344	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation).	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070679	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Multiple organ dysfunction syndrome (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation).	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070608	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	No	Abdominal pain (n/a - Unknown -), Chest pain (n/a - Unknown -), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100070697	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070721	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070840	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070952	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070875	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070879	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070870	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070942	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070949	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100070944	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100077188	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Aortic aneurysm rupture (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])	BIATORPROST (BIATORPROST) (C - n/a - n/a - [n/a - n/a - n/a]), BUPRENORPHINE (C - n/a - n/a - [n/a - n/a - n/a]), CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - n/a - n/a - [n/a - 10mg - n/a]), CLOPIDOGREL, CLOPIDOGREL BESILATE (C - n/a - n/a - [n/a - 75mg - n/a]), FLEOPIRNE (C - n/a - n/a - [n/a - n/a - n/a]), HYDROCORTISONE ACETATE, LIDOCANE, LIDOCANE, HYDROCORTISONE ACETATE PH. EUR. (C - n/a - n/a - [n/a - n/a - n/a]), MACROGOL 4000 (C - n/a - n/a - [n/a - 10DF] - n/a), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a])	ICSR
EU-EC-100077185	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	TRIMBOV (BECLOMETHASONE DIPROPIONATE, GLYCOPHYRANUM BROMIDE, FORMOTEROL FLUMARATE DIIHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLCHOLINE] (C - n/a - n/a - [n/a - 200mg - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [BISOPROLOL, BISOPROLOL FLUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [CINACOUZUMAB] (C - n/a - n/a - [n/a - 1mg - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100079372	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	EBXA (MEMANTINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, FLUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE DINTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100079377	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100079463	23/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Pulmonary oedema (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079379	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079743	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079943	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - n/a - Not applicable - [n/a - n/a - n/a]), [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (C - Gouty arthritis - Not applicable - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [DONEPEZIL, DONEPEZIL HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - 10mg - Oral]), [LOGSARTAN, LOGSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral])	ICSR
EU-EC-100079262	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown - Results in Death), Fatigue (n/a - Unknown - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079828	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Sepsis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100079870	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079843	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079871	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100079804	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Female	No	Corns (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Disturbance in attention (n/a - Fatal - Results in Death), Peripheral vascular disorder (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	CLOPIDOGREL, [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), ENTRESTO [VALSARTAN, SACUBITRIL] (C - n/a - n/a - [n/a - n/a - n/a]), CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100079719	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079719	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079787	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079741	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Male	No	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Epilepsy (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079837	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079435	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079483	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening), Rectal haemorrhage (n/a - Unknown - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079504	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100079690	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [2M - n/a - Intramuscular])	[FUROSEMIDE] (C - Cardiac failure - n/a - [10d - n/a - Intravenous (not otherwise specified)])	ICSR
EU-EC-100079824	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079745	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079753	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079831	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079830	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079833	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079645	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079651	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079699	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079698	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079696	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100079697	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death			

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Country for Regulatory Purposes	Primary Source Country for Economic Area	Literature Reference	Patent Age Class (as per report)	Patent Specified	Patent Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chnr - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
			Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Heart rate decreased (n/a - Unknown - Other Medically Important Condition)		LANTUS [INSULIN LARGINE] (C - Diabetes mellitus - n/a - [n/a - 30kU] - Subcutaneous), LURASIDONE HYDROCHLORIDE [LURASIDONE HYDROCHLORIDE] (C - Schizophrenia - n/a - [n/a - 120mg - Oral], [ACETYSALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral], [ATENLOL, ATENOLOL BP] (C - Essential hypertension - n/a - [n/a - 25mg - Oral], [ATORVASTATIN CALCIUM] (C - Hyperlipidemia - n/a - [n/a - 40mg - Oral], [FINASTERIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - 5mg - Oral], [HALOPERIDOL] (C - Schizophrenia - n/a - [n/a - 10mg - Oral], [HYPROMOLLOSE, GLYCEROL, MACROGOL 400, POLYVINYL ALCOHOL, PROPYLENE GLYCOL, VASELINE, LIQUID PARAFFIN] (C - Dry eye - n/a - [n/a - 4mg] - Ophthalmic), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 80ug - Oral], [LITHIUM CARBONATE] (C - Schizophrenia - n/a - [n/a - 900mg - Oral], [LORAZEPAM] (C - Anxiety, Restlessness - n/a - [n/a - 1mg - Oral], [LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral], [MISOPROLOL] (C - Gastroesophageal reflux disease - n/a - [n/a - 20mg - Oral], [PARACETAMOL] (C - Pain - n/a - [n/a - 300mg - Oral], [SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 200mg - Oral], [TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - 8mg - Oral], [VITAMIN D] (C - Supplementation therapy - n/a - [n/a - 200kIU] - Oral)		
EU-EC-1000762578	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Vertigo (n/a - Unknown - Results in Death), Vomiting (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000762621	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000762714	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000762754	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 pneumonia (S) - Fatal - Results in Death, Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000763020	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death), Blood glucose decreased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000763054	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Blood glucose decreased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])	NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TRAJENTA 5 MG FILM-COATED TABLETS [BILAGLIPTIN] (C - n/a - n/a - [n/a - 5mg - n/a]), [AMLODIPINE] (C - n/a - n/a - [n/a - 5mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 8mg - n/a]), [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [ECOSAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 10DF] - n/a), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 500mg - n/a]), [PANTOPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000763019	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])		ICSR	
EU-EC-1000763114	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000763264	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-1000763681	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	[BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 1DF] - n/a), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROPRAZOLE] (C - n/a - n/a - [n/a - 25mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 75ug - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MISOPROLOL] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [OXCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [OXCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PHOSPHATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - 50mg - n/a])	ICSR	
EU-EC-1000763710	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Livedly (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000763735	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000763729	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Blood pressure immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Breath sounds (n/a - Unknown -), Choking (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Recovered/Resolved -), Oxygen saturation immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Pulse (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - n/a)	[LORAZEPAM] (C - Drug hypersensitivity - n/a - [n/a - 10mg - n/a])	ICSR	
EU-EC-1000763817	14/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Cough - n/a - [n/a - 100mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Cough - n/a - [n/a - n/a - Respiratory inhalation])	ICSR	
EU-EC-1000763887	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Subleuk (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763907	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763920	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763929	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763930	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763940	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Cerebrovascular accident (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763949	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763975	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763943	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000763975	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-1000763982	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (S) - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-1000763976	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Gaze palsy (n/a - Fatal - Results in Death), Ophthalmoscopy (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	EXELON [RIVASTIGMINE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral], MELATONIN [MELATONIN] (C - Sleep disorder - n/a - [n/a - n/a - Oral], [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - Oral], [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEFUMARATE] (C - Hypertension - n/a - [n/a - n/a - Oral], [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral], [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastroesophageal disorder prophylaxis - n/a - [n/a - n/a - Oral], [ISOSORBIDE MONONITRATE, ISOSORBIDE MONONITRATE] (C - Hypertension - n/a - [n/a - n/a - Oral], [MEMENTINE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral], [MIRTAZAPINE] (C - Insomnia - n/a - [n/a - n/a - Oral], [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral], [RISPERIDONE] (C - Behaviour disorder - n/a - [n/a - n/a - Oral], [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral], [COAPROVEL 150 MG/12.5 MG TABLETS HYDROCHLOROTHIAZIDE, IRIBESARTAN] (C - n/a - n/a - [n/a - n/a - Oral], [MANSERIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral], [NEBIVOLOL] (C - n/a - n/a - [n/a - 1DF] - Oral], [OXAZEPAM] (C - n/a - n/a - [n/a - 1DF] - Oral], [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 75mg - Oral], [ZOPICLONE] (C - n/a - n/a - [n/a - 1DF] - Oral)	ICSR	
EU-EC-1000763982	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular), HEPRA 300 MG FILM-COATED TABLETS [LEVETIRACETAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYSALICYLATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [FUROSEMIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [METFORMIN, METFORMIN HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [OXAZEPAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80-90%] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), [TIAPRIDE HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 145mg - Oral], [ZOPICLONE] (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000764027	11/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Asthma (S) - Fatal - Results in Death), Chills (S) - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (S) - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000764069	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000764061	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (24h - Fatal - Results in Death), General physical condition abnormal (24h - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-1000764072	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000764071	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3mL - n/a])	[LEVOCETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OLMESARTAN MEDOXOMIL, AMLODIPINE, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ROBUVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOPROPRIDOL, TIOPROPRIDOL BROMIDE, TIOPROPRIDOL BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000764074	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	[VALSARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000764028	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Lip oedema (n/a - Recovering/Resolving - Results in Death), Pyrexia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - 125mg - Oral], [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 25ug - Oral])	ICSR	
EU-EC-1000764029	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Coronavirus infection (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovering/Resolving - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000764031	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000764039	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular])	[LUMIGAN [Bimatoprost]] (C - n/a - n/a - [n/a - n/a - Ophthalmic), [PROLIS BENSODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - Transdermal], [CARBONER, CARBONER 8749] (C - n/a - n/a - [n/a - n/a - Ophthalmic), [FLUTICASON, FLUTICASON, FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL XINAIPATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Oral], [LACTULOSE] (C - n/a - n/a - [n/a - n/a - Oral], [MACROGOL 4000] (C - n/a - n/a - [n/a - n/a - Oral], [MEMENTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral], [METOPROLOLAM, METOPROLOLAM HYDROCHLORIDE, METOPROLOLAM HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR	

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Report	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000752841	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), 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 - [1d - n/a - n/a])	(SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - 1DF] - n/a)	ICSR
EU-EC-1000753163	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000753413	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	CELLEPT (MYPHENOLATE MOFETIL) (C - Renal transplant - n/a - [n/a - 2g - n/a]), CICLOSPORIN (CICLOSPORIN) (C - Renal transplant - n/a - [n/a - 75mg - n/a]), NOT AVAILABLE (C - Aorta coarctation repair - n/a - [n/a - n/a - n/a]), VALSARTAN, SACUBITRIL (VALSARTAN, SACUBITRIL) (C - Hypertension - n/a - [n/a - n/a - n/a]), (BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - Hypertension - n/a - [n/a - 5mg - n/a]), (METHYLPRENESOLONE, METHYLPRENESOLONE SODIUM SUCCINATE) (C - Renal transplant - n/a - [n/a - 2mg - n/a]), (TORASEMIDE) (C - Cardiac failure - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-1000753420	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000751578	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000751575	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000751594	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ABILEY 10 MG TABLETS (ARIPIPRAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]), (BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]), (HYDROXYCHLOROQUINE SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (NICARDIPINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (RAMIPRIL) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000751630	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000751634	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000751646	04/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000751628	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000751820	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute myocardial infarction (MI - Fatal - Results in Death), Death (MI - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	(ACETYLSALICYLIC ACID) (C - n/a - n/a -), (BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]), (BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]), (BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]), (PERINDOPRIL, PERINDOPRIL ARGININE, PERINDOPRIL TERT-BUTYLAMINE) (C - n/a - n/a -), (ROSVASTATIN, ROSUVASTATIN CALCIUM) (C - n/a - n/a -), (TRIMETAZIDINE DIHYDROCHLORIDE) (C - n/a - n/a -)	ICSR
EU-EC-1000752904	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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])	Not reported	ICSR
EU-EC-1000753560	03/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anxiety (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Pneumia (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (LORAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000750735	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Cardiac failure (3d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypertension (3d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000748953	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000748964	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000748927	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000749033	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000749033	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007490796	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	(LISINAPRIL) (C - Hypertension - n/a - [n/a - 5mg - Oral]), (METHAMIZOLE SODIUM) (C - Analgesic therapy, Antiflammatory therapy - n/a - [2d - 200mg] - Oral), (METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE) (C - n/a - n/a - [1d - 50mg] - Oral), (NEXCOCODONE HYDROCHLORIDE, NEXCOCODONE HYDROCHLORIDE DIHYDRATE) (C - Analgesic therapy, Antiflammatory therapy - n/a - [1d - 10DF] - Oral), (PARACETAMOL) (C - Analgesic therapy, Antiflammatory therapy - n/a - [n/a - 500mg - Oral]), (SALICILIC ACID) (C - Agitation - n/a - [2d - 20mg - Oral - More in CSR]), (SULFAMETHOXAZOLE, TRIMETHOPRIM) (C - Antibiotic therapy - n/a - [n/a - 2DF] - Oral), (SULFAMETHOXAZOLE, TRIMETHOPRIM) (C - Antibiotic therapy - n/a - [n/a - 4mg - Oral]), (FRAMIDOLAN HYDROCHLORIDE) (C - Analgesic therapy, Antiflammatory therapy - n/a - [1d - 200mg] - Oral - More in CSR), (FRAMIDOLAN HYDROCHLORIDE) (C - Analgesic therapy, Antiflammatory therapy - n/a - [1d - 200mg] - Oral - More in CSR)	ICSR
EU-EC-10007493759	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	(HYDROCHLOROTHIAZIDE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007494159	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007494307	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (8d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007494983	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007498569	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	(CLOMETHAZOLE, CLOMETHAZOLE EDSILATE) (C - n/a - n/a - [n/a - n/a - n/a]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]), (ZOPICLONE) (C - n/a - n/a - [n/a - n/a - n/a]), (TRALENTA 5 MG FILM-COATED TABLETS (LUNGLEPTIN) (C - n/a - n/a - [n/a - 5mg - n/a]), (BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA) (C - n/a - n/a - [n/a - 1DF] - n/a), (BISOPROLOL FUMARATE) (C - n/a - n/a - [n/a - 2.5mg - n/a]), (BUCESONIDE, FORMOTEROL FUMARATE DIHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (CINCHOCANINE HYDROCHLORIDE, PREDNISOLONE CAPROATE) (C - n/a - n/a - [n/a - n/a - n/a]), (COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE) (C - n/a - n/a - [n/a - 1DF] - n/a), (COLECALCIFEROL) (C - n/a - n/a - [n/a - 800µg - n/a]), (CYANOCOBALAMIN) (C - n/a - n/a - [n/a - 1mg - n/a]), (PERDORS SULFATE) (C - n/a - n/a - [n/a - 100mg - n/a]), (FOLIC ACID) (C - n/a - n/a - [n/a - 1mg - n/a]), (FUROSEMIDE) (C - n/a - n/a - [n/a - 40mg - n/a]), (GLYCERYL TRINITRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (LACTULOSE, LACTULOSE LIQUID) (C - n/a - n/a - [n/a - n/a - n/a]), (MAGNESIUM CITRATE, MAGNESIUM LACTATE) (C - n/a - n/a - [n/a - 120mg - n/a]), (OMEPRAZOLE) (C - n/a - n/a - [n/a - 20mg - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (PROPYLENE GLYCOL) (C - n/a - n/a - [n/a - n/a - n/a]), (SALBUTAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (SODIUM PICOSUFATE, SODIUM PICOSUFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (TIOPROPURINOL BROMIDE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007498124	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])	(SODIUM PICOSUFATE, SODIUM PICOSUFATE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007479399	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007479649	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Anal haemorrhage (n/a - Unknown -), Back pain (n/a - Recovered/Resolved -), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	(ACETYLSALICYLIC ACID) (C - n/a - n/a - [n/a - 100mg - Oral]), (HYDROXYCARBAMIDE) (C - Myelofibrosis neoplasm - n/a - [n/a - 1500mg - Oral]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - n/a - n/a - [n/a - 5mg - Oral]), (TORASEMIDE SODIUM) (C - n/a - n/a - [n/a - 100mg - Oral])	ICSR
EU-EC-10007481768	01/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007480253	01/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	General physical condition abnormal (22d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007480217	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	(COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE) (C - Supplementation therapy - n/a - [n/a - n/a - Oral]), (METHANIL - HYDROCHLORIDE) (C - Dermatita Agnata's type - n/a - [n/a - n/a - Oral]), (DIAZEPAM) (C - Relaxation therapy, Sleep disorder - n/a - [n/a - n/a - Oral]), (MDAZOLAM, MDIAZOLAM, MDIAZOLAM HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (ANTIFOAM M COMPOUND, DIMETICONE, DIMETICONE, COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS, SILICA, COLLOIDAL ANHYDROUS, DIMETICONE 100X) (C - n/a - n/a - [n/a - n/a - n/a]), (EPHEDRINE BITARTRATE, LIDOCAINE HYDROCHLORIDE, LIDOCAINE, LIDOCAINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (FLUTICASON PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, FLUTICASON PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE PH EUR) (C - n/a - n/a - [n/a - n/a - n/a]), (GLYCEROL) (C - n/a - n/a - [n/a - n/a - n/a]), (GLYCOPYRROLUM BROMIDE, GLYCOPYRROLUM BROMIDE, NESTOXIMINE METHYL SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (HALOPERIDOL, HALOPERIDOL DECANOATE) (C - n/a - n/a - [n/a - n/a - n/a]), (MOMETASON FURATE) (C - n/a - n/a - [n/a - n/a - n/a]), (MOMETASON FURATE) (C - n/a - n/a - [n/a - n/a - n/a]), (MORPHINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (SODIUM PICOSUFATE, SODIUM PICOSUFATE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007486658	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Hypertensive emergency (n/a - Recovered/Resolved - Other Medically Important Condition), Pain (1d - Unknown - Other Medically Important Condition), Rains (n/a - Unknown -), Somnolence (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death), Wheezing (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007487006	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Wheezing (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	AZOFT (BRINZOLAMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (ACETYLSALICYLIC ACID) (C - n/a - n/a - [n/a - 75mg - n/a]), (CITALOPRAM) (C - n/a - n/a - [n/a - 10mg - n/a]), (CYANOCOBALAMIN) (C - n/a - n/a - [n/a - 1mg - n/a]), (PENTANYL, PENTANYL CITRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (FOLIC ACID) (C - n/a - n/a - [n/a - 1mg - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (GABAPENTIN) (C - n/a - n/a - [n/a - 100mg - n/a]), (LATANOPROLET) (C - n/a - n/a - [n/a - n/a - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - n/a - n/a - [n/a - 50mg - n/a]), (MDAZOLAM, MDIAZOLAM HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (MORPHINE, MORPHINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007477398	31/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007473306	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007473313	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007474006	30/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (23d - Fatal - Results in Death), Pyrexia (23d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [23d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007474085	30/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (5d - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death), Influenza like illness (5d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007481769	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007481911	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007481994	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007483995	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Body temperature increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Tumor (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-1		

EU Local Number	EY Category/Report Date	Report Type	Primary Source/Qualification	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form		
EU-EC-10007467137	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	KETOCONAZOLE (METOCONAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]); PROLIA (DENOSUMAB) (C - n/a - n/a - [n/a - n/a - n/a]); RESOLOR (RUCLOLOPRIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (BENSAZIDE HYDROCHLORIDE, LEVODOPA, BENSAZIDE, LEVODOPA) (C - n/a - n/a - [n/a - n/a - n/a]); (BUPRENORPHINE) (C - n/a - n/a - [n/a - n/a - n/a]); (CABERGOLIN, LEVODOPA) (C - n/a - n/a - [n/a - n/a - n/a]); (CLOZAPINE) (C - n/a - n/a - [n/a - n/a - n/a]); (COLCALSIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]); (CYMOCOSALAMIN) (C - n/a - n/a - [n/a - n/a - n/a]); (DUCLOSATE SODIUM, SORBITOL (E402)) (C - n/a - n/a - [n/a - n/a - n/a]); ECONAZOLE, ECONAZOLE NITRATE, ECONAZOLE NITRATE, ZINC OXIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (FOLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]); (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]); (LACTULOSE) (C - n/a - n/a - [n/a - n/a - n/a]); (MIDOCORNE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]); (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]); (POTASSIUM CHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (PROPYLENE GLYCOL) (C - n/a - n/a - [n/a - n/a - n/a]); (SODIUM PICOSULFATE) (C - n/a - n/a - [n/a - n/a - n/a]); (CHLORHEXIDINE) (C - n/a - n/a - [n/a - n/a - n/a]); (CTULOPRAM) (C - n/a - n/a - [n/a - n/a - n/a]); (LACTULOSE, LACTULOSE LIQUID) (C - n/a - n/a - [n/a - 20mL - n/a]); (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - 50ug - n/a]); (MEMANTINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 20mg - n/a]); (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]); (RISPERIDONE) (C - n/a - n/a - [n/a - 25mg - n/a]); (SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL (E402), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DRYDRATE) (C - n/a - n/a - [n/a - n/a - Rectal]); (SODIUM FLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (TIMOLOL, FLOCARPINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - Ophthalmic]); (TIMOLOL) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007467491	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	(SODIUM PICOSULFATE) (C - n/a - n/a - [n/a - n/a - n/a]); (CHLORHEXIDINE) (C - n/a - n/a - [n/a - n/a - n/a]); (CTULOPRAM) (C - n/a - n/a - [n/a - n/a - n/a]); (LACTULOSE, LACTULOSE LIQUID) (C - n/a - n/a - [n/a - 20mL - n/a]); (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - 50ug - n/a]); (MEMANTINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 20mg - n/a]); (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]); (RISPERIDONE) (C - n/a - n/a - [n/a - 25mg - n/a]); (SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL (E402), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DRYDRATE) (C - n/a - n/a - [n/a - n/a - Rectal]); (SODIUM FLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (TIMOLOL, FLOCARPINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - Ophthalmic]); (TIMOLOL) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007470797	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007471240	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1 (DF) - n/a])	Not reported	ICSR
EU-EC-10007451396	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1 (DF) - Intramuscular])	Not reported	ICSR
EU-EC-10007452321	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007452962	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007456951	23/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Prophylaxis - n/a - [n/a - Unknown])	Not reported	ICSR
EU-EC-10007458677	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	FIASP (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a]); TRESIBA (INSULIN DEGLUCINE) (C - n/a - n/a - [n/a - n/a - n/a]); LATINOL (ATENOLOL BP) (C - n/a - n/a - [n/a - n/a - n/a]); (DOPENE) (C - n/a - n/a - [n/a - n/a - n/a]); (DRIED FERROUS SULFATE, FERROUS SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]); (LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]); (THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007440963	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1 (DF) - Intramuscular])	Not reported	ICSR
EU-EC-10007440966	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1 (DF) - Intramuscular])	(AMODIARONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 200mg - Oral]); (BISOPROLOL FUMARATE) (C - n/a - n/a - [n/a - 1.25mg - Oral]); (FLINDIONE) (C - n/a - n/a - [n/a - Oral]); (FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL XINAFOATE) (C - n/a - n/a - [n/a - Respiratory (inhalation)]); (FUROSEMIDE) (C - n/a - n/a - [n/a - 40mg - Oral]); (LATANOPROST) (C - n/a - n/a - [n/a - n/a - Ophthalmic]); (MORPHINE SULFATE) (C - n/a - n/a - [n/a - n/a - Oral]); (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - Oral]); (STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM) (C - n/a - n/a - [n/a - n/a - Rectal]); (ALPACOLAM) (C - n/a - n/a - [n/a - n/a - n/a]); (COLCALSIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]); (STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM) (C - n/a - n/a - [n/a - n/a - n/a]); LIXIANA (EDOXABAN, EDOXABAN TOSYLATE) (C - n/a - n/a - [n/a - 300mg - n/a]); (COLCALSIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]); (FOLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]); (FUROSEMIDE) (C - n/a - n/a - [n/a - 20mg - n/a]); (SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (ZOLPIDEM, ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 10mg - n/a]); (CLOPIDOGREL, CLOPIDOGREL, BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]); (LORAZEPAM) (C - n/a - n/a - [n/a - 2.5mg - n/a]); (TRACAZOLONE, TRACAZOLONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - 8mg - n/a]); (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - 12.5mg - n/a])	ICSR
EU-EC-10007441212	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Increased bronchial secretion (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), (PENTANYL) (S - Pain - Does not changed - [n/a - 0.12mg - Transdermal])	(STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM) (C - n/a - n/a - [n/a - n/a - n/a]); LIXIANA (EDOXABAN, EDOXABAN TOSYLATE) (C - n/a - n/a - [n/a - 300mg - n/a]); (COLCALSIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]); (FOLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]); (FUROSEMIDE) (C - n/a - n/a - [n/a - 20mg - n/a]); (SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (ZOLPIDEM, ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 10mg - n/a]); (CLOPIDOGREL, CLOPIDOGREL, BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]); (LORAZEPAM) (C - n/a - n/a - [n/a - 2.5mg - n/a]); (TRACAZOLONE, TRACAZOLONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - 8mg - n/a]); (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - 12.5mg - n/a])	ICSR
EU-EC-10007444663	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 1 (DF) - n/a])	(STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM) (C - n/a - n/a - [n/a - n/a - n/a]); LIXIANA (EDOXABAN, EDOXABAN TOSYLATE) (C - n/a - n/a - [n/a - 300mg - n/a]); (COLCALSIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]); (FOLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]); (FUROSEMIDE) (C - n/a - n/a - [n/a - 20mg - n/a]); (SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (ZOLPIDEM, ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 10mg - n/a]); (CLOPIDOGREL, CLOPIDOGREL, BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]); (LORAZEPAM) (C - n/a - n/a - [n/a - 2.5mg - n/a]); (TRACAZOLONE, TRACAZOLONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - 8mg - n/a]); (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - 12.5mg - n/a])	ICSR
EU-EC-10007444664	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening), Fatigue (n/a - Fatal - Results in Death, Life Threatening), Sore throat (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 1 (DF) - n/a])	(STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM) (C - n/a - n/a - [n/a - n/a - n/a]); LIXIANA (EDOXABAN, EDOXABAN TOSYLATE) (C - n/a - n/a - [n/a - 300mg - n/a]); (COLCALSIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]); (FOLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]); (FUROSEMIDE) (C - n/a - n/a - [n/a - 20mg - n/a]); (SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (ZOLPIDEM, ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 10mg - n/a]); (CLOPIDOGREL, CLOPIDOGREL, BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]); (LORAZEPAM) (C - n/a - n/a - [n/a - 2.5mg - n/a]); (TRACAZOLONE, TRACAZOLONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - 8mg - n/a]); (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - 12.5mg - n/a])	ICSR
EU-EC-10007448602	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 1 (DF) - n/a])	(STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM) (C - n/a - n/a - [n/a - n/a - n/a]); LIXIANA (EDOXABAN, EDOXABAN TOSYLATE) (C - n/a - n/a - [n/a - 300mg - n/a]); (COLCALSIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]); (FOLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]); (FUROSEMIDE) (C - n/a - n/a - [n/a - 20mg - n/a]); (SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (ZOLPIDEM, ZOLPIDEM TARTRATE) (C - n/a - n/a - [n/a - 10mg - n/a]); (CLOPIDOGREL, CLOPIDOGREL, BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]); (LORAZEPAM) (C - n/a - n/a - [n/a - 2.5mg - n/a]); (TRACAZOLONE, TRACAZOLONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 50mg - n/a]); (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - 8mg - n/a]); (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - 12.5mg - n/a])	ICSR
EU-EC-10007448203	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007454910	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007446819	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), General physical condition abnormal (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007446863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	(ATORVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]); (BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]); (HYDROCHLOROPROPAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]); (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]); (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]); (RAMIPRIL) (C - n/a - n/a - [n/a - n/a - n/a]); (WARFARIN SODIUM) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007446871	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007446887	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	(ACETYLSALICYLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]); (FINASTERIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (VITAMINE, VITAMINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]); (PRACZETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]); JANUVA 100 MG FILM-COATED TABLETS (SITAGLIPTIN) (C - n/a - n/a - [n/a - n/a - Oral]); MMPARA 30 MG FILM-COATED TABLETS (CINACALCET, CINACALCET HYDROCHLORIDE) (C - n/a - n/a - [n/a - 30mg - Oral]); (AMOXICILLIN SODIUM, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN POTASSIUM CLAVULANATE) (C - n/a - n/a - [n/a - 1g - Oral]); (ATORVASTATIN, ATORVASTATIN CALCIUM) (C - n/a - n/a - [n/a - 20mg - Oral]); (BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - 5mg - Oral]); (BENETHAMINE SODIUM PICOSULFATE) (C - n/a - n/a - [n/a - 5mg - Oral]); (DISODIUM PHOSPHATE, ANHYDROUS, CALCIUM MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, DISODIUM PHOSPHATE, ANHYDROUS, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BIPHENYLDIPHOSPHATE) MONOHYDRATE, DISODIUM PHOSPHATE, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BIPHENYLDIPHOSPHATE) MONOHYDRATE (C - n/a - n/a - [n/a - 500mg - Oral]); (ENALAPRIL, ENALAPRIL MALEATE) (C - n/a - n/a - [n/a - 5mg - Oral]); (OXAZEPAM) (C - n/a - n/a - [n/a - 10mg - Oral]); (PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - n/a - n/a - [n/a - n/a - Oral]); (TINZAPARIN, TINZAPARIN SODIUM) (C - Anal fibrillation - n/a - [n/a - 7mL - Subcutaneous])	ICSR
EU-EC-10007431098	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1 (DF) - Intramuscular])	(ATORVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]); (BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]); (HYDROCHLOROPROPAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]); (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]); (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]); (RAMIPRIL) (C - n/a - n/a - [n/a - n/a - n/a]); (WARFARIN SODIUM) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007431177	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1 (DF) - Intramuscular])	Not reported	ICSR
EU-EC-10007431178	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1 (DF) - Intramuscular])	Not reported	ICSR
EU-EC-10007423553	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Blood pressure immeasurable (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Personality change (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007433960	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	(DORZOLAMIDE, TIMOLOL) (C - n/a - n/a - [n/a - n/a - n/a]); (LATANOPROST) (C - n/a - n/a - [n/a - n/a - n/a]); (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - 25ug - n/a]); (PARACETAMOL) (C - n/a - n/a - [n/a - 1000mg - n/a]); (SODIUM PICOSULFATE) (C - n/a - n/a - [n/a - n/a - n/a]); (UREA) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007436279	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007422470	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Agitation (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1 (DF) - n/a])	Not reported	ICSR
EU-EC-10007423215	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007423313	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007423721	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007423826	25/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available								

EU Local Number	EY Category	Report Type	Primary Source	Primary Source Country	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age Group (as per report)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chx - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000740363	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000740374	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	Death (n/a - Fatal - Results in Death), Decreased appetite (0d - Fatal - Results in Death), Diarrhoea (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000740423	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-1000740476	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-1000740543	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Not Specified	Death (n/a - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000741019	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Male	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-1000741429	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	Death (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000741430	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation), Reususcitation (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000741431	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	Not Specified	Death (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation), Pyrexia (0d - Unknown - Results in Death, Caused Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000738048	20/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Female	Not Specified	Admission (n/a - Not Recovered/Not Resolved -), Confusional state (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hemiparesis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Right ventricular enlargement (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000738058	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000734216	18/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000737096	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000737624	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000737616	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	Not Specified	Death (1d - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Livido reticularis (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Peripheral oedema (n/a - Fatal - Results in Death), Respiratory rate increased (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	BUMETANIDE (BUMETANIDE) (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN (MELATONIN) (C - n/a - n/a - [n/a - n/a - n/a]), ACETYLCHOLINE (C - n/a - n/a - [n/a - n/a - n/a]), ATORVASTATIN (C - n/a - n/a - [n/a - n/a - n/a]), BISOPROLOL (BISOPROLOL) (C - n/a - n/a - [n/a - n/a - n/a]), CASSIA (C - n/a - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - n/a - n/a - [n/a - n/a - n/a]), DIMETICONE (C - n/a - n/a - [n/a - n/a - n/a]), DOXUSILATE SODIUM (C - n/a - n/a - [n/a - n/a - n/a]), DOXYCYCLINE HYCLATE (C - n/a - n/a - [n/a - n/a - n/a]), ISOSORBIDE MONONITRATE (C - n/a - n/a - [n/a - n/a - n/a]), MACROGOL 3350 (C - n/a - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - n/a - n/a - [n/a - n/a - n/a]), PARACETAMOL CODONE PHOSPHATE (C - n/a - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - n/a - n/a - [n/a - n/a - n/a]), SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350 (C - n/a - n/a - [n/a - n/a - n/a]), TRAMADOL (TRAMADOL) (C - n/a - n/a - [n/a - n/a - n/a]), TRAZADINE (C - n/a - n/a - [n/a - n/a - n/a]), ATORVASTATIN (C - n/a - n/a - [n/a - n/a - n/a]), FURUSEMIDE, FURUSEMIDE SODIUM (C - n/a - n/a - [n/a - 20mg - n/a]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - n/a - n/a - [n/a - 75ug - n/a]), METOPROLOL, METOPROLOL TARTRATE (C - n/a - n/a - [n/a - 100mg - n/a]), OXAZEPAM (C - n/a - n/a - [n/a - 5mg - n/a]), RAMIPRIL (C - n/a - n/a - [n/a - n/a - n/a]), IWARFARIN SODIUM (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000737676	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000736487	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000736793	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	AERUS 1 MG FILM COATED TABLET (DESLORATADINE) (C - n/a - n/a - [n/a - 5mg - n/a]), ARANESP 30 MICROGRAMS SOLUTION FOR INJECTION (DARBEPOETIN ALFA) (C - n/a - n/a - [n/a - 1DF] - n/a), ACETYLCHOLINE (C - n/a - n/a - [n/a - n/a - n/a]), ALLOPURINOL (C - n/a - n/a - [n/a - 100mg - n/a]), BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE (C - n/a - n/a - [n/a - n/a - n/a]), CARBOMER (C - n/a - n/a - [n/a - n/a - n/a]), DALTEPARIN SODIUM (C - n/a - n/a - [n/a - 1DF] - n/a), FINASTERIDE (C - n/a - n/a - [n/a - 5mg - n/a]), FURUSEMIDE (C - n/a - n/a - [n/a - 250mg - n/a]), FURUSEMIDE (C - n/a - n/a - [n/a - n/a - n/a]), GLYCEROL (C - n/a - n/a - [n/a - n/a - n/a]), GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION 10 % (C - n/a - n/a - [n/a - n/a - n/a]), GLYCOPYRRONIUM BROMIDE (C - n/a - n/a - [n/a - 1mL - n/a]), HALOPERIDOL (C - n/a - n/a - [n/a - n/a - n/a]), HYPERMUCILLONE (C - n/a - n/a - [n/a - n/a - n/a]), LAMIVUDINE (C - n/a - n/a - [n/a - n/a - n/a]), MEXILETAM HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), MORPHINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), OMEPRazole (C - n/a - n/a - [n/a - 10mg - n/a]), OXAZEPAM (C - n/a - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - n/a - n/a - [n/a - 1000mg - n/a]), POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350 (C - n/a - n/a - [n/a - n/a - n/a]), SODIUM PICOSULFATE, SODIUM PICOSULFATE (C - n/a - n/a - [n/a - n/a - n/a]), SODIUM POLYSTYRENE SULPHONATE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000736292	17/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000736746	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	Not Specified	Cardiac fibrillation (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown - Results in Death), Syncope (n/a - Unknown - Results in Death), Vomiting (n/a - Unknown - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000736102	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-1000734624	14/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000734683	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000734742	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	ELIQUIS (APIXIBAN) (C - Thrombosis prophylaxis - n/a - [n/a - 5mg - Oral]), ATORVASTATIN (C - Cardiovascular event prophylaxis - n/a - [n/a - 80mg - Oral]), DORIPENEM (C - n/a - n/a - [n/a - 10mg - Oral]), METOPROLOL SUCCINATE, METOPROLOL TARTRATE (C - Heart rate irregular - n/a - [n/a - 25mg - Oral]), IRISFERONE (C - Aggression - n/a - [n/a - 25mg - Oral]), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Depression - n/a - [n/a - 50mg - Oral]), TAMISULON HYDROCHLORIDE (C - Dysuria - n/a - [n/a - 4mg - Oral])	ICSR
EU-EC-1000733563	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Phylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000733595	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Caused Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused Prolonged Hospitalisation), Resuscitation (n/a - Fatal - Results in Death, Life Threatening, Caused Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000733936	12/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	Not Specified	Death (1d - Fatal - Results in Death), Malaise (n/a - Unknown - Results in Death), Vomiting (n/a - Unknown - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000731844	08/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	CARVEDILOL (C - n/a - n/a - [n/a - 25mg - n/a]), CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - n/a - n/a - [n/a - 20mg - n/a]), COLECALCIFEROL, CALCIUM COLECALCIFEROL, CALCIUM CARBONATE (C - n/a - n/a - [n/a - 1DF] - n/a), FURUSEMIDE (C - n/a - n/a - [n/a - n/a - n/a]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - n/a - n/a - [n/a - 100ug - n/a]), PARACETAMOL (C - n/a - n/a - [n/a - 1000mg - n/a]), PIRENIDINE (C - n/a - n/a - [n/a - n/a - n/a]), RIBAVIRIN (C - n/a - n/a - [n/a - n/a - n/a]), RIFAMPICIN (C - n/a - n/a - [n/a - n/a - n/a]), RIFABUTIN (C - n/a - n/a - [n/a - n/a - n/a]), RIFAPYRIDINE (C - n/a - n/a - [n/a - n/a - n/a]), RIFAMPIN (C - n/a - n/a - [n/a - n/a - n/a]), RIFAMPIN SODIUM (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000731051	07/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (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])	Not reported	ICSR
EU-EC-1000730781	06/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Condition aggravated (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BETMGA (MRABEGRON) (C - n/a - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [n/a - n/a - n/a]), ALODIPINE, ALODIPINE BESILATE, ALODIPINE MALEATE (C - n/a - Not applicable - [n/a - n/a - n/a]), CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE (C - n/a - Not applicable - [n/a - n/a - n/a]), COLECALCIFEROL, CYANOCOBALAMIN, ERGOCALCIFEROL, RETINOL ACETATE, ERGOCALCIFEROL, TOCOPHERYL ACETATE (C - n/a - Unknown -), CYANOCOBALAMIN (C - n/a - Not applicable - [n/a - n/a - n/a]), ENALAPRIL, ENALAPRIL MALEATE (C - n/a - Not applicable - [n/a - n/a - n/a]), ESCITALOPRAM, ESCITALOPRAM OXALATE (C - n/a - Not applicable - [n/a - n/a - n/a]), ESTRADIOL, ESTRADIOL HEMHYDRATE (C - n/a - Not applicable - [n/a - n/a - n/a]), FOLIC ACID (C - n/a - Not applicable - [n/a - n/a - n/a]), LACTOBACILLUS ACIDOPHILUS, BIFIDOBACTERIUM SP (C - n/a - Not applicable - [n/a - n/a - n/a]), NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE (C - n/a - Not applicable - [n/a - n/a - n/a]), OXAZEPAM (C - n/a - Not applicable - [n/a - n/a - n/a]), QUETIAPINE, QUETIAPINE FUMARATE (C - n/a - Not applicable - [n/a - n/a - n/a]), RISPERIDONE (C - n/a - Not applicable - [n/a - n/a - n/a]), RYTHMOL (C - n/a - Not applicable - [n/a - n/a - n/a])	ICSR
EU-EC-1000730626	06/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	Not reported	ICSR
EU-EC-1000728616	05/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Phylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000729196	04/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (0d - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Phylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000729208	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	Not Specified	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Phylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000728310	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR