

EU Local Number	EV Gateway Review Date	Report Type	Primary Cause Qualification	Primary Country Regulatory Authority	Literature Reference	Patent Age Group	Patent Age Group (as per report)	Patent Sex	Patent DMF Report	Reaction List PT (Duration 7 Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Class - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/ Administered Drug List (Drug Class - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
										Myocardial necrosis marker increased (N - Fatal - Results in Death), Prosthetic cardiac valve thrombosis (N - Fatal - Results in Death), Renal impairment (N - Fatal - Results in Death), Cardiovascular accident (N - Fatal - Results in Death), Death (N - Fatal - Results in Death), Sepsis (N - Fatal - Results in Death), COVID-19 (N - Fatal - Results in Death), Death (N - Fatal - Results in Death), SARS-CoV-2 test positive (N - Fatal - Results in Death), Vaccination failure (N - Fatal - Results in Death)			
EU-EC-100156801	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No		COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])		Not reported
EU-EC-100156805	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No		COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])		Not reported
EU-EC-100156806	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No		COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - 3mL - Intramuscular])	VORIRENT (PAZOPANIB, PAZOPANIB HYDROCHLORIDE) (C - N/A - N/A -)	CSR
EU-EC-100156913	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (N/A - Fatal - Results in Death, Other Medically Important Condition), Immunisation (N/A - Fatal - Results in Death), Interchange of vaccine products (N/A - Fatal - Results in Death), Off label use (N/A - Unknown -), Product on issue (N/A - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - N/A])	(AMOXICILLIN, AMOXICILLIN TRIHYDRATE) (C - Lower respiratory tract infection - N/A - [P/ - N/A - N/A]), (INFLUENZA VIRUS) (C - Immunisation - N/A - [1d - N/A - N/A])	CSR
EU-EC-100156925	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Cardiac failure (N/A - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (N/A - Unknown -), Death (N/A - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (N/A - Unknown - Life Threatening, Other Medically Important Condition), Dyspnoea (N/A - Unknown - Other Medically Important Condition), Pneumonia (N/A - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - 15DF - Intramuscular])		Not reported
EU-EC-100156971	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Male	No	Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - 15DF - Intramuscular])		Not reported
EU-EC-100156973	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Female	No	Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - 15DF - Intramuscular])		Not reported
EU-EC-100156945	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	No	Death (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Limb ischaemia (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Melaena (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (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
EU-EC-100156921	08/11/2021	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 - Intramuscular])		Not reported
EU-EC-100156729	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Amylase increased (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Blood creatinine increased (N/A - Not Recovered/Not Resolved - Other Medically Important Condition), Blood glucose increased (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), C-reactive protein increased (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemoglobin decreased (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Leucocytes (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rales (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sinus tachycardia (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - N/A - Not applicable - [N/A - N/A - Intramuscular])		Not reported
EU-EC-100156782	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest pain (N/A - Fatal - Results in Death), Death (N/A - Fatal - Results in Death), Dyspnoea exertional (N/A - Fatal - Results in Death), Fibrin D dimer increased (N/A - Fatal - Results in Death), Hypoxia (N/A - Fatal - Results in Death), Hypoxynormotensive episode (N/A - Fatal - Results in Death), Pain (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - N/A - N/A - [N/A - 3mL - Intramuscular])		Not reported
EU-EC-100156783	08/11/2021	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 - [N/A - 15DF - Intramuscular])		Not reported
EU-EC-100156978	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Death (N/A - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - N/A - N/A - [N/A - N/A])		Not reported
EU-EC-100156910	08/11/2021	Spontaneous	Non Healthcare Professional	Non 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, Other Medically Important Condition), 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
EU-EC-100156904	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death), Hemiparesis (N/A - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - N/A - N/A - [N/A - N/A])		Not reported
EU-EC-100156939	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - N/A - [N/A - Intramuscular])		Not reported
EU-EC-100156911	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac 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 - [1d - N/A - N/A])		Not reported
EU-EC-100156710	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Liver function test abnormal (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (N/A - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - N/A - [N/A - N/A])		Not reported
EU-EC-100156140	08/11/2021	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 - 20DF - N/A])		Not reported
EU-EC-100156528	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardiac failure (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cone (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)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - N/A])	LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - N/A - N/A - [100µg - N/A])	CSR
EU-EC-100156426	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death), Haemoptysis (N/A - Unknown - Other Medically Important Condition), Hives (N/A - Unknown - Other Medically Important Condition), Interchange of vaccine products (N/A - Unknown -), Loss of consciousness (N/A - Unknown - Other Medically Important Condition), Off label use (N/A - Unknown -), Pain (N/A - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])		Not reported
EU-EC-100156404	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardio-respiratory arrest (N/A - Unknown - Life Threatening, Other Medically Important Condition), Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - N/A])		Not reported
EU-EC-100156414	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiovascular disorder (N/A - Fatal - Results in Death), Death (N/A - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - Intramuscular])		Not reported
EU-EC-100156445	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Cardiac failure acute (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 - Intramuscular])		Not reported
EU-EC-100156405	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Cardio-respiratory arrest (N/A - Unknown - Life Threatening, Other Medically Important Condition), Cholelithiasis (N/A - Unknown -), Death (N/A - Fatal - Results in Death), Subglottic oedema (N/A - Unknown - Other Medically Important Condition), Movement disorder (N/A - Unknown - Other Medically Important Condition), Nausea (N/A - Unknown - Other Medically Important Condition), Pericardial effusion (N/A - Unknown - Other Medically Important Condition), Strabismus (N/A - Unknown -), Thrombosis (N/A - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - 3mL - N/A])		Not reported
EU-EC-100156421	08/11/2021	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 - 15DF - Intramuscular])		Not reported
EU-EC-100156487	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death, Other Medically Important Condition), Headache (N/A - Unknown -), Melaena (N/A - Not Recovered/Not Resolved -), Myocardial infarction (N/A - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - Intramuscular])	(ACETYSALICYLIC ACID) (C - N/A - N/A - [N/A - 100mg - Oral]), (AMODIPINE BESILATE) (C - N/A - N/A - [N/A - 2.5mg - Oral]), (CARBOCISTEINE) (C - N/A - N/A - [N/A - 500mg - Oral]), (CLARITHROMYCIN) (C - N/A - N/A - [N/A - 400mg - Oral]), (ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM) (C - N/A - N/A - [N/A - 20mg - Oral]), (ROSUVASTATIN, ROSUVASTATIN CALCIUM) (C - N/A - N/A - [N/A - 5mg - Oral])	CSR
EU-EC-100156448	08/11/2021	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 - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])		Not reported
EU-EC-100156190	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Female	No	Asthma (N/A - Unknown -), Death (N/A - Unknown - Other Medically Important Condition), Hypoglycaemia (N/A - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - N/A - [N/A - N/A])		Not reported
EU-EC-100156147	08/11/2021	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, Other Medically Important Condition), Thrombosis (N/A - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])		Not reported
EU-EC-100156187	08/11/2021	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])		Not reported
EU-EC-100156219	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Female	No	Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 15DF - Intramuscular])		Not reported
EU-EC-1001563214	08/11/2021	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])		Not reported
EU-EC-100156327	08/11/2021	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 - 20DF - N/A])		Not reported
EU-EC-100156361	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - N/A - [N/A - 20DF - N/A])		Not reported
EU-EC-100156487	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	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), Cardiovascular accident (N/A - Unknown - Life Threatening, Other Medically Important Condition), Chest pain (N/A - Unknown - Life Threatening, Other Medically Important Condition), Cone (N/A - Unknown - Life Threatening, Other Medically Important Condition), Death (N/A - Fatal - Results in Death, Other Medically Important Condition), Dyspareunia (N/A - Unknown - Life Threatening, Other Medically Important Condition), Hemiparesis (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), Tissue necrosis (N/A - Unknown - Life Threatening, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - Intramuscular])		Not reported
EU-EC-100156426	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Arthralgia (N/A - Unknown -), Cerebral haemorrhage (N/A - Unknown - Other Medically Important Condition), Cerebral thrombosis (N/A - Unknown - Other Medically Important Condition), Cone (N/A - Unknown - Other Medically Important Condition), Death (N/A - Fatal - Results in Death), Dyspareunia (N/A - Unknown -), Fibrosis (N/A - Unknown -), Impotence (N/A - Unknown -), Melaena (N/A - Unknown -), Neck pain (N/A - Unknown -), Pain in extremity (N/A - Unknown -), Viral infection (N/A - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - N/A])		Not reported
EU-EC-100156480	29/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Smith, L. Cerebral venous sinus thrombosis after COVID-19 vaccination. High-resolution CT-scanning. 2021;6(1):38	18-64 Years	Not Specified	Male	No	Cerebral venous sinus thrombosis (N/A - Unknown - Other Medically Important Condition), Death (N/A - Fatal - Results in Death, Other Medically Important Condition), Fibrin D dimer increased (N/A - Unknown - Other Medically Important Condition), Headache (N/A - Unknown - Other Medically Important Condition), Hot nerve paresthesia (N/A - Unknown - Other Medically Important Condition), Muscular weakness (N/A - Unknown - Other Medically Important Condition), Paresis (N/A - Unknown - Other Medically Important Condition), Platelet count decreased (N/A - Unknown - Other Medically Important Condition), Platelet factor 4 (N/A - Unknown - Other Medically Important Condition), Visual impairment (N/A - Unknown - Other Medically Important Condition)	(METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE) (S - Thrombotic thrombocytopenic purpura - Unknown - [N/A - N/A - Intravenous (not otherwise specified)])		Not reported
EU-EC-100156876	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - N/A - [N/A - 20DF - N/A])		Not reported
EU-EC-100156866	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Chills (214 - Fatal - Results in Death), Death (214 - Fatal - Results in Death), Fibrosis (214 - Fatal - Results in Death), Melaena (214 - Fatal - Results in Death), Nausea (214 - Fatal - Results in Death), Pyrexia (214 - Fatal - Results in Death), Respiratory failure (214 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])		Not reported
EU-EC-100156836	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Body temperature increased (N/A - Unknown -), Condition aggravated (N/A - Unknown -), Death (N/A - Fatal - Results in Death), Hypoxia (N/A - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (N/A - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [N/A - 3mL - Intramuscular])	DUOPILAVIN 75 MG/100 MG FILM-COATED TABLETS (ACETYSALICYLIC ACID, CLOPIDOGREL) (C - N/A - Unknown - [N/A - N/A - Oral]), (DIPYRIDAMOLE) (C - N/A - Unknown - [N/A - 400mg - Oral]), (BISOPROLOL, FENAMATE, BISOPROLOL, FENAMATE, ACETYSALICYLIC ACID, BISOPROLOL, HOEMIFENAMATE) (C - Cardiac failure chronic - Unknown - [N/A - 2.5mg - Oral]), (SPRONOLACTONE) (C - Essential hypertension - Unknown - [N/A - 25mg - Oral]), (VALSARTAN, AMLODIPINE, HYDROCHLOROTHIAZIDE) (C - Essential hypertension - Unknown - [N/A - N/A - Oral])	CSR
EU-EC-100156846	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - N/A - [N/A - Intramuscular])		Not reported
EU-EC-100156936	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death, Other Medically Important Condition), Interchange of vaccine products (N/A - Unknown -), Off label use (N/A - Unknown -), Somnolence (N/A - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - N/A - N/A])	XARELTO (RIVAROXABAN) (C - Thrombosis - N/A - [N/A - Oral]), (AMODIPINE HYDROCHLORIDE) (C - Hypertension - N/A - [N/A - Oral]), (DOBUTAMINE, HESPERIDINE) (C - Cardiovascular disorder - N/A - [N/A - N/A - Oral]), (VITAMINS MNC) (C - Supplement therapy - N/A - [N/A - Oral])	CSR
EU-EC-100156704	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute hyponatremia (N/A - Fatal - Results in Death), Death (N/A - Fatal - Results in Death), Focal oedema (N/A - Fatal - Results in Death), Neuropenia (N/A - Fatal - Results in Death), Pulmonary embolism (N/A - Fatal - Results in Death), Thrombocytopenia (N/A - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])	(ANNEXOSIN, LEVOTHYROXINE SODIUM) (C - N/A - Unknown - [N/A - 10DF - N/A]), (EUCALCALFEDIC) (C - N/A - Unknown - [N/A - 10DF - N/A]), (PHENTONIN SODIUM) (C - N/A - Unknown - [N/A - 200mg - N/A]), (VALPROIC ACID, SODIUM VALPROATE) (C - N/A - Unknown - [N/A - 2250mg - N/A])	CSR
EU-EC-100156713	29/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	No	COVID-19 (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [N/A - N/A - N/A])		Not reported

EU Local Number	EV Summary Report Date	Report Type	Primary Country	Primary Regulatory Authority	Literature Reference	Patent (EU)	Patent (Other)	Patent (Other)	Patent (Other)	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)	CSR Form
EU-EC-1001047134	26/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	SARS-CoV-2 test positive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute myocardial infarction (MI) (via - Fatal - Results in Death), Cardiovascular disorder (MI - Fatal - Results in Death), Chest discomfort (MI - Fatal - Results in Death), Crisis (MI - Fatal - Results in Death), Coronary artery occlusion (MI - Fatal - Results in Death), Death (MI - Fatal - Results in Death), Myocardial infarction (MI - Fatal - Results in Death), Myocardial infarction (MI - Fatal - Results in Death), Pneumonia (MI - Fatal - Results in Death), Pyrexia (MI - Fatal - Results in Death), Respiratory disorder (MI - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001047135	26/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	SARS-CoV-2 test positive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute myocardial infarction (MI) (via - Fatal - Results in Death), Cardiovascular disorder (MI - Fatal - Results in Death), Chest discomfort (MI - Fatal - Results in Death), Crisis (MI - Fatal - Results in Death), Coronary artery occlusion (MI - Fatal - Results in Death), Death (MI - Fatal - Results in Death), Myocardial infarction (MI - Fatal - Results in Death), Myocardial infarction (MI - Fatal - Results in Death), Pneumonia (MI - Fatal - Results in Death), Pyrexia (MI - Fatal - Results in Death), Respiratory disorder (MI - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	ACETYLSALICYLIC ACID (C - via - Unknown - [via - via - via]), FRAMADOL, TRAMADOL, HYDROCODONE (C - Back pain - Unknown - [via - via - via])	C38
EU-EC-1001047216	26/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Coronary artery occlusion (MI - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dyspnoea (via - Fatal - Results in Death), Feeling abnormal (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001047247	26/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001047471	26/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Cardiovascular accident (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Crisis (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coronary artery occlusion (via - Unknown -), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (via - Unknown - Other Medically Important Condition), Hypotension (via - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001047504	26/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Cyanosis (MI - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dyspnoea (MI - Fatal - Results in Death), Nervous system disorder (MI - Fatal - Results in Death), Pain in extremity (via - Fatal - Results in Death), Peripheral oedema (MI - Fatal - Results in Death), Sedation (MI - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	AMLODIPINE, AMLODIPINE BESILATE (C - via - Unknown - [via - 10DF - via]), BISOPROLOL, BISMUTH, BISOPROLOL, HEMIFUMARATE (C - via - Unknown - [via - 10DF - via]), BRILINTANIDE (C - via - Unknown - [via - 10DF - via]), ESICATOPRAN, ESCICATOPRAN OXALATE (C - via - Unknown - [via - 10DF - via]), PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE (C - via - Unknown - [via - 10DF - via]), SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350 (C - via - Unknown - [via - 10DF - via]), SPRONOLACTONE (C - via - Unknown - [via - 10DF - via])	C38
EU-EC-1001047505	26/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Not Specified	Abnormal joint aspirate (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Amygdala (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Breast pain (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Phonemia (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - via - [via - via - via])	Not reported	C38
EU-EC-1001046966	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046908	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	Not Specified	Blood pressure increased (via - Unknown -), Cardiovascular disorder (via - Unknown -), Death (via - Fatal - Results in Death), Dyspnoea (via - Recovered/Resolved -), Syncope (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	DARBEFETIN ALFA (DARBEFETIN ALFA) (C - Nephropatic anaemia - via - [110 - via - via - Intensive (not otherwise specified)], EPOETIN ALFA, EPOETIN ALFA (C - Nephropatic anaemia - via - [11 - via - via - Intensive (not otherwise specified)], ACETYLSALICYLIC ACID (C - Prophylaxis - via - [via - via - Oral]), ACICLOMANTADINE, DIPHENHYDRAZINE (C - Dermatitis contact - via - [via - via - Topical]), ALFACALCIDIOL (C - Chronic kidney disease-mineral and bone disorder - via - [via - via - Oral]), BIFEDOLAM (C - Insomnia - via - [via - via - Oral]), CALCIUM CARBONATE (C - Chronic kidney disease-mineral and bone disorder - via - [via - via - Oral]), CARVEDILOL (C - Hypertension - via - [via - via - Oral]), FERRIC CITRATE (C - Chronic kidney disease-mineral and bone disorder - via - [via - via - Oral]), IRBESARTAN (C - Hypertension - via - [via - via - Oral]), LANZOPRAZOLE (C - Prophylaxis - via - [via - via - Oral]), LIDOCANE, PRILICANE, PRILICANE HYDROCHLORIDE, LIDOCANE HYDROCHLORIDE (C - Local anaesthesia - via - [via - 2g - Topical]), NIFEDIPINE (C - Hypertension - via - [via - via - Oral]), NIFEDIPINE (C - Hypertension - via - [via - via - Oral]), SERRVOSE, LAM (C - Constipation - via - [via - via - Oral])	C38
EU-EC-1001046674	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death), Fall (via - Not Recovered/Not Resolved -), Gulfian-Barre syndrome (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (via - Not Recovered/Not Resolved -), Parosmia (via - Not Recovered/Not Resolved -), Somnolence (via - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046199	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Not Specified	COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (MI - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	NOT AVAILABLE (C - via - Unknown - [via - 1g - via]), ACETYLSALICYLIC ACID (C - via - Unknown - [via - 100mg - via]), ATORVASTATIN CALCIUM (C - via - Unknown - [via - 80mg - via]), BAGLUFEN (C - via - Unknown - [via - 50DF - via]), BISOPROLOL, BISOPROLOL FUMARATE (C - via - Unknown - [via - 2.5mg - via]), FENOFIBRATE (C - via - Unknown - [via - 200mg - via]), GABAPENTIN (C - via - Unknown - [via - 200mg - via]), OMEPRAZOLE (C - via - Unknown - [via - 40mg - via]), PROFENONE HYDROCHLORIDE (C - via - Unknown - [via - 150mg - via])	C38
EU-EC-1001046225	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046473	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Arrhythmia (via - Fatal - Results in Death), Cardiovascular disorder (via - Fatal - Results in Death), Coronary artery disease (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Thrombosis (via - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 3ml - Intramuscular])	CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - Angina pectoris - via - [via - via - Oral]), ACETYLSALICYLIC ACID (C - Angina pectoris - via - [via - via - Oral]), BACILLUS SUBTILIS LACTAM, BIFIDOBACTERIA (C - via - via - [via - via - Oral]), BISOPROLOL, BISOPROLOL FUMARATE (C - Angina pectoris - via - [via - via - Oral]), LAFUTONE (C - Gastroesophageal reflux disease - via - [via - via - Oral]), MAGNESIUM OXIDE (C - Constipation - via - [via - via - Oral]), PARACETAMOL (C - via - via - [via - via - via])	C38
EU-EC-1001046292	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 10DF - Intramuscular])	ANALGET METFORMIN HYDROCHLORIDE, STATPLATIN METFORMIN HYDROCHLORIDE, STATPLATIN PHOSPHATE, METFORMIN HYDROCHLORIDE, STATPLATIN PHOSPHATE MONOHYDRATE (C - via - via - [via - via - Oral]), ACETYLSALICYLIC ACID, GLYCINE, ACETYLSALICYLIC ACID (C - via - via - [via - via - Oral]), ATORVASTATIN (C - via - via - [via - via - Oral]), CLOPIDOGREL (C - via - via - [via - via - Peritardol]), FLUOROURACIL, FLUOROURACIL SODIUM (C - via - via - [via - via - Oral]), GEMFIBROZIL (C - via - via - [via - via - Oral]), METOPROLOL SUCCINATE, METOPROLOL TARTRATE (C - via - via - [via - via - Oral]), RAMIPRIL (C - via - via - [via - via - Oral])	C38
EU-EC-1001046200	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Death (1 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - via - [1 - via - 3ml - Intramuscular]), ACETYLSALICYLIC ACID, D,L-TYROSINE, ACETYLSALICYLIC ACID (S - Angina pectoris - via - [via - 100mg - Oral]), BISOPROLOL, HEMIFUMARATE (S - Angina pectoris - via - [via - 10DF - Oral]), LACTULOSE LIQUID (S - via - via - [via - via - Oral])	Not reported	C38
EU-EC-1001046382	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	Not Specified	COVID-19 (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Drug ineffective (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046435	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Not Specified	Not Specified	Arrhythmia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac disorder (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046382	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	COVID-19 (via - Not Recovered/Not Resolved - Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Immobilisation (via - Unknown -), Of test side (via - Unknown -), Product not listed (via - Unknown -), Vomiting (via - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	APIXABAN (APIXABAN) (C - Anal infection - via - [via - via - via]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALATE, AMLODIPINE MESILATE (C - Hypertension - via - [via - via - via]), BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL, HEMIFUMARATE (C - Anal infection - via - [via - via - via]), DANESARTAN (C - Hypertension - via - [via - via - via]), ELONAZEPAM (C - via - via - [via - via - via]), FERROUS SULFATE (C - Anemia - via - [via - via - via]), FLUOREMIDE (C - via - via - [via - via - via]), INFLUENZA VIRUS (C - Immunisation - via - [via - via - via]), MIRTAZAPINE (C - via - via - [via - via - via]), OMEPRAZOLE (C - via - via - [via - via - via]), SERTALINE, SERTALINE HYDROCHLORIDE (C - via - via - [via - via - via])	C38
EU-EC-1001046310	26/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Death (MI - Fatal - Results in Death), Pyrexia (MI - Fatal - Results in Death), Asthma (MI - Fatal - Results in Death), Autonomic nervous system disorder (MI - Fatal - Results in Death), Bladder disorder (MI - Fatal - Results in Death), Bedridden (MI - Fatal - Results in Death), Cerebral nervous system lesion (MI - Fatal - Results in Death), Cognitive disorder (MI - Fatal - Results in Death), Death (MI - Fatal - Results in Death), Dyspnoea (MI - Fatal - Results in Death), Feeling abnormal (MI - Fatal - Results in Death), Mouth dysfunction (MI - Fatal - Results in Death), Nervous system disorder (MI - Fatal - Results in Death), Skin disorder (MI - Fatal - Results in Death), Speech disorder (MI - Fatal - Results in Death), Spontaneous haemorrhage (MI - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - via - [via - 10DF - Intramuscular])	Not reported	C38
EU-EC-1001041380	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death), Feeling cold (via - Unknown - Caused/Prolonged Hospitalisation), Headache (via - Unknown - Caused/Prolonged Hospitalisation), Myalgia (via - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (via - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - via - [via - via - via])	Not reported	C38
EU-EC-1001039412	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Not Specified	Cardiac arrest (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death), Dyspnoea (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (via - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Rash (via - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - via - [via - via - via])	EXFORGE (VALSARTAN, AMLODIPINE, VALSARTAN, AMLODIPINE BESILATE) (C - via - via - [via - via - Oral])	C38
EU-EC-1001047150	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death), Immature granulocyte count increased (via - Unknown -), Neutrophil count increased (via - Unknown -), Pneumonia (via - Recovered/Resolved - Other Medically Important Condition), White blood cell count increased (via - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046391	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	Not Specified	Circulatory collapse (via - Unknown - Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Immobilisation (via - Unknown -), Of test side (via - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046224	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death), Males (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 10DF - Intramuscular])	Not reported	C38
EU-EC-1001046306	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Not Specified	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - via - [via - 10DF - Intramuscular])	Not reported	C38
EU-EC-1001046307	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Not Specified	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 10DF - Intramuscular])	Not reported	C38
EU-EC-1001046302	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Not Specified	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - via - [via - 10DF - Intramuscular])	Not reported	C38
EU-EC-1001046316	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Not Specified	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 10DF - Intramuscular])	Not reported	C38
EU-EC-1001046403	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death), Lung disorder (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046426	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death), Erythema (via - Unknown -), Gait disturbance (via - Unknown -), Influenza (via - Unknown -), Intestinal obstruction (via - Unknown - Other Medically Important Condition), Pain (via - Unknown -), Swamp disorder (via - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001046480	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	Not reported	C38
EU-EC-1001047165	27/10/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	Not Specified	Confusional state (via - Unknown -), Death (via - Fatal - Results in Death, Other Medically Important Condition), Fatigue (via - Not Recovered/Not Resolved -), Mood decreased (via - Unknown -), Speech disorder (via - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])	ACETYLSALICYLIC ACID (C - via - via - [via - 100mg - Oral]), CALCIUM CARBONATE, CHOLECALCIFEROL, CONCENTRATE POWDER FORM, COLECALCIFEROL, CALCIUM CARBONATE (C - via - via - [via - via - Oral]), DISODIUM PHOSPHATE, ANHYDROUS SODIUM HYDROGEN PHOSPHATE ANHYDROUS (C - via - via - [via - via - Oral]), ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE (C - via - via - [via - 44.5mg - Oral]), FERRIC CARBOXYMALTOSE, IRON (C - via - via - [via - via - Male in ESR]), FOLIC ACID (C - via - via - [via - via - Oral]), HEPARIN CALCIUM (C - via - via - [via - via - Subcutaneous]), IPRAFENOFAN, IPRAFENOFAN SULFAMATE (C - via - via - [via - via - Respiratory (inhalation)], IPRAFENOFAN, IPRAFENOFAN, CODEINE PHOSPHATE, HEMIFUMARATE (C - via - via - [via - via - Oral]), SODIUM PHOSPHATE, SODIUM PHOSPHATE, SODIUM PHOSPHATE MONOHYDRATE (C - via - via - [via - via - Oral]), SODIUM PHOSPHATE, SODIUM PHOSPHATE, SODIUM PHOSPHATE MONOHYDRATE (C - via - via - [via - via - Oral]), SORBITOL, EXO, FXI (C - via - via - [via - via - Oral]), TORSEMIDE (C - via - via - [via - via - Oral]), ZYPREXA ELANAPARNE (C - via - via - [via - via - Oral]), ALFADOLAME (C - via - via - [via - via - Oral]), LEVOHYDROXYMETHYL SODIUM (C - via - via - [via - via - Oral])	C38
EU-EC-1001038366	27/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	Not Specified	Brain death (via - Fatal - Results in Death, Other Medically Important Condition), Cerebral disorder (via - Fatal - Results in Death, Other Medically Important Condition), Cerebral venous thrombosis (via - Fatal - Results in Death, Other Medically Important Condition), Crisis (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - via - [via - 10DF - via])	Not reported	C38

EU Lead Number	EV Reference Number	Report Type	Primary Country of Origin	Literature Reference	Patent (EU Group)	Patent (EU Country)	Patent (EU Person)	Patent (EU Firm)	Reaction List PT (Duration 7 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))	CRP Form
EU-EC-100104637	20/09/2021	Sponaneous	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 - 10DF] - Intramuscular)	Not reported	C18
EU-EC-100104643	20/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (20a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	C18
EU-EC-100104657	20/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	Chest discomfort (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10DF] - Intramuscular)	Not reported	C18
EU-EC-100104656	20/09/2021	Sponaneous	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 - Not applicable - [1d - 10DF] - Intramuscular)	Not reported	C18
EU-EC-100104694	20/09/2021	Sponaneous	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 - 10DF] - Intramuscular)	Not reported	C18
EU-EC-100104842	20/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (3d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3dL - Intramuscular)	ACICLOVIR (ACICLOVIR) (C - n/a - n/a -)	C18
EU-EC-100104843	20/09/2021	Sponaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	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)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001051420	20/09/2021	Sponaneous	Non 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 - n/a])	ATORVASTATIN (C - n/a - n/a - [n/a - n/a - n/a])	C18
EU-EC-1001051475	20/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001053015	27/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	C18
EU-EC-1001053033	27/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001053032	27/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Somnolence (5d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 3DF] - n/a])	Not reported	C18
EU-EC-1001053040	27/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (3d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular)	PANTOPRAZOLE (PANTOPRAZOLE), PANTOPRAZOLE SODIUM SESQUIHYDRATE (C - n/a - n/a -), ALPRADOLAM (C - n/a - n/a -), BUCSIZONAMIDE (C - n/a - n/a -), CALCIUM CITRATE, MAIZE STARCH, STEARIC ACID, TALC, CALCIUM CITRATE (C - n/a - n/a -), ENOXAPARIN SODIUM (C - n/a - n/a -), FOLIC ACID BP, DRIED FERROUS SULPHATE BP, FOLIC ACID, DRIED FERROUS SULFATE, FOLIC ACID, FERROUS SULFATE (C - n/a - n/a -), LEVOTHYROXINE SODIUM (C - n/a - n/a -), MESALAZINE (C - n/a - n/a -), NEMOVIDOL (C - n/a - n/a -), PEGSODIUM SODIUM (C - n/a - n/a -), SINGULIRED (C - n/a - n/a -)	C18
EU-EC-1001041151	27/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular)	Not reported	C18
EU-EC-1001041435	27/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular)	Not reported	C18
EU-EC-1001041452	27/09/2021	Sponaneous	Non 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	C18
EU-EC-1001042276	24/09/2021	Sponaneous	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	C18
EU-EC-1001042427	24/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Acute ischaemia (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	C18
EU-EC-1001043016	24/09/2021	Sponaneous	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 - [1d - 10DF] - Intramuscular)	Not reported	C18
EU-EC-1001043095	24/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001043097	24/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 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	C18
EU-EC-1001043066	23/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	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	C18
EU-EC-1001043079	23/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular)	Not reported	C18
EU-EC-1001043080	23/09/2021	Sponaneous	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 - n/a - n/a])	Not reported	C18
EU-EC-1001041147	23/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Aspiration (n/a - Unknown -), Death (3d - Fatal - Results in Death), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown -), Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Headache (n/a - Not Recovered/Not Resolved -), Movement disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - not applicable - [n/a - 3dL - Intramuscular)	Not reported	C18
EU-EC-1001041191	23/09/2021	Sponaneous	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 - n/a - [n/a - 10DF] - Intramuscular)	Not reported	C18
EU-EC-1001009364	22/09/2021	Sponaneous	Healthcare Professional	Non 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 - n/a - Unknown)	Not reported	C18
EU-EC-1001009300	22/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001009312	22/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Acute ischaemia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001009343	22/09/2021	Sponaneous	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	C18
EU-EC-1001009345	22/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Cerebral venous thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Pain (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Rash (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	C18
EU-EC-1001009362	22/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dystonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001009188	22/09/2021	Sponaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	Accidental overdose (5d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability), Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Gastroesophageal reflux disease (5d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability), Interchange of vaccine products (5d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability), Lymphoma (5d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability, Other Medically Important Condition), Victim of abuse (5d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disability)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), COVID-19 MRNA VACCINE MODERNA (CX-02414) COVID-19 MRNA VACCINE MODERNA (CX-02414) (C - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Unknown)	Not reported	C18
EU-EC-1001009336	22/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	Death (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	C18
EU-EC-1001009376	22/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	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	C18
EU-EC-1001009312	22/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Elderly	Female	Chest pain (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])	PANACEA (MAGNESIUM HYDROXIDE) (C - Pan - Not applicable - [n/a - n/a - Oral]), (TRAMADOL HYDROCHLORIDE) (C - Pan - Not applicable - [n/a - 150mg - Oral])	C18
EU-EC-1001009161	22/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspareunia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001009142	22/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001009188	22/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Not Specified	Death (n/a - Fatal - Results in Death), Muscle spasms (n/a - Unknown -), Myalgia (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001009870	22/09/2021	Sponaneous	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	C18
EU-EC-1001009847	22/09/2021	Sponaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	C18
EU-EC-1001009861	22/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown)	Not reported	C18
EU-EC-1001009745	22/09/2021	Sponaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Cerebral infection (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 - Intramuscular)	CÉLECOXIB (CÉLECOXIB) (C - n/a - n/a - [n/a - 20DF] - Oral), HELIUM 3/4/6/7/8/9/10/11/12/13/14/15/16/17/18/19/20/21/22/23/24/25/26/27/28/29/30/31/32/33/34/35/36/37/38/39/40/41/42/43/44/45/46/47/48/49/50/51/52/53/54/55/56/57/58/59/60/61/62/63/64/65/66/67/68/69/70/71/72/73/74/75/76/77/78/79/80/81/82/83/84/85/86/87/88/89/90/91/92/93/94/95/96/97/98/99/100/101/102/103/104/105/106/107/108/109/110/111/112/113/114/115/116/117/118/119/120/121/122/123/124/125/126/127/128/129/130/131/132/133/134/135/136/137/138/139/140/141/142/143/144/145/146/147/148/149/150/151/152/153/154/155/156/157/158/159/160/161/162/163/164/165/166/167/168/169/170/171/172/173/174/175/176/177/178/179/180/181/182/183/184/185/186/187/188/189/190/191/192/193/194/195/196/197/198/199/200/201/202/203/204/205/206/207/208/209/210/211/212/213/214/215/216/217/218/219/220/221/222/223/224/225/226/227/228/229/230/231/232/233/234/235/236/237/238/239/240/241/242/243/244/245/246/247/248/249/250/251/252/253/254/255/256/257/258/259/260/261/262/263/264/265/266/267/268/269/270/271/272/273/274/275/276/277/278/279/280/281/282/283/284/285/286/287/288/289/290/291/292/293/294/295/296/297/298/299/300/301/302/303/304/305/306/307/308/309/310/311/312/313/314/315/316/317/318/319/320/321/322/323/324/325/326/327/328/329/330/331/332/333/334/335/336/337/338/339/340/341/342/343/344/345/346/347/348/349/350/351/352/353/354/355/356/357/358/359/360/361/362/363/364/365/366/367/368/369/370/371/372/373/374/375/376/377/378/379/380/381/382/383/384/385/386/387/388/389/390/391/392/393/394/395/396/397/398/399/400/401/402/403/404/405/406/407/408/409/410/411/412/413/414/415/416/417/418/419/420/421/422/423/424/425/426/427/428/429/430/431/432/433/434/435/436/437/438/439/440/441/442/443/444/445/446/447/448/449/450/451/452/453/454/455/456/457/458/459/460/461/462/463/464/465/466/467/468/469/470/471/472/473/474/475/476/477/478/479/480/481/482/483/484/485/486/487/488/489/490/491/492/493/494/495/496/497/498/499/500/501/502/503/504/505/506/507/508/509/510/511/512/513/514/515/516/517/518/519/520/521/522/523/524/525/526/527/528/529/530/531/532/533/534/535/536/537/538/539/540/541/542/543/544/545/546/547/548/549/550/551/552/553/554/555/556/557/558/559/560/561/562/563/564/565/566/567/568/569/570/571/572/573/574/575/576/577/578/579/580/581/582/583/584/585/586/587/588/589/590/591/592/593/594/595/596/597/598/599/600/601/602/603/604/605/606/607/608/609/610/611/612/613/614/615/616/617/618/619/620/621/622/623/624/625/626/627/628/629/630/631/632/633/634/635/636/637/638/639/640/641/642/643/644/645/646/647/648/649/650/651/652/653/654/655/656/657/658/659/660/661/662/663/664/665/666/667/668/669/670/671/672/673/674/675/676/677/678/679/680/681/682/683/684/685/686/687/688/689/690/691/692/693/694/695/696/697/698/699/700/701/702/703/704/705/706/707/708/709/710/711/712/713/714/715/716/717/718/719/720/721/722/723/724/725/726/727/728/729/730/731/732/733/734/735/736/737/738/739/740/741/742/743/744/745/746/747/748/749/750/751/752/753/754/755/756/757/758/759/760/761/762/763/764/765/766/767/768/769/770/771/772/773/774/775/776/777/778/779/780/781/782/783/784/785/786/787/788/789/790/791/792/793/794/795/796/797/798/799/800/801/802/803/804/805/806/807/808/809/810/811/812/813/814/815/816/817/818/819/820/821/822/823/824/825/826/827/828/829/830/831/832/833/834/835/836/837/838/839/840/841/842/843/844/845/846/847/848/849/850/851/852/853/854/855/856/857/858/859/860/861/862/863/864/865/866/867/868/869/870/871/872/873/874/875/876/877/878/879/880/881/882/883/884/885/886/887/888/889/890/891/892/893/894/895/896/897/898/899/900/901/902/903/904/905/906/907/908/909/910/911/912/913/914/915/916/917/918/919/920/921/922/923/924/925/926/927/928/929/930/931/932/933/934/935/936/937/938/939/940/941/942/943/944/945/946/947/948/949/950/951/952/953/954/955/956/957/958/959/960/961/962/963/964/965/966/967/968/969/970/971/972/973/974/975/976/977/978/979/980/9	

EU Lead Number	EV Gateway Review Date	Report Type	Primary Country	Primary Country Regulatory Purpose	Literature Reference	Patent Age Group	Patent Age Group (per report)	Patent Sex	Patent Age	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)	CSR Form
EU-EC-1001016742	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (01 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	LEVOTHYROXINE SODIUM (C - Hypothyroidism - na - [na - 100ug - Oral])	CSR
EU-EC-1001030021	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (01 - Fatal - Results in Death, Other Medically Important Condition), Infection (na - Fatal - Results in Death, Other Medically Important Condition), Muscle weakness (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition), Myopia (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition), Oedema peripheral (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (na - Fatal - Results in Death, Other Medically Important Condition), Respiratory failure (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition), Septic shock (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition), Sten infection (na - Fatal - Results in Death, Other Medically Important Condition) Anaphylaxis (01 - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - 10d] - Intramuscular)	AMLODIPINE, AMLODIPINE BESILATE (C - Hypertension - na - [na - na - Oral]), BROMAZEPAM (C - Hypertension - na - [na - na - Oral]), PROMETHELIN, PROMETHELIN HYDROCHLORIDE (C - Tachyarrhythmia - na - [na - na - Oral]), SERITRALINE HYDROCHLORIDE (C - Depression - na - [na - na - Oral])	CSR
EU-EC-1001030227	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (01 - Fatal - Results in Death, Other Medically Important Condition), Dyspnea (01 - Fatal - Results in Death, Other Medically Important Condition), Gullain-Barre syndrome (01 - Fatal - Results in Death, Other Medically Important Condition), Muscle weakness (na - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - 10d] - Intramuscular)		CSR
EU-EC-1001021986	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1001024065	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)		CSR
EU-EC-1001025278	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	ARIPRAZOLE (ARIPRAZOLE) (C - na - na -)	CSR
EU-EC-1001030619	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR
EU-EC-1001000000	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Not Specified	Cardiac arrest (na - Not Recovered/Not Resolved - Caused/Not Specified Hospitalisation, Other Medically Important Condition), Death (na - Fatal - Results in Death, Other Medically Important Condition), Eye movement disorder (na - Unknown - Caused/Not Specified Hospitalisation), Feeling abnormal (na - Unknown -), Organ failure (na - Unknown - Caused/Not Specified Hospitalisation), Pyrrolis (na - Unknown -), Secure (na - Not Recovered/Not Resolved - Caused/Not Specified Hospitalisation, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	BACLOFEN (C - na - na - [na - 20mg - na]), DILTIAZEM (C - na - na - [na - 40mg - na]), EUCALYPTUS OIL (C - na - na - [na - 5mg - na]), GABAPENTIN (C - na - na - [na - 400mg - na])	CSR
EU-EC-1001000929	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])		CSR
EU-EC-1001000670	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition), Dyspnoea (na - Unknown - Caused/Not Specified Hospitalisation), Renal disorder (na - Unknown - Caused/Not Specified Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])		CSR
EU-EC-1001000160	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Elderly	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR
EU-EC-1001000023	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death), Pericardial effusion (na - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR
EU-EC-1001015461	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death), Fatigue (na - Not Recovered/Not Resolved - Other Medically Important Condition), Hypogonadism (na - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR
EU-EC-1000999729	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000999163	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Acute respiratory distress syndrome (na - Unknown - Caused/Not Specified Hospitalisation, Other Medically Important Condition), COVID-19 (na - Unknown - Caused/Not Specified Hospitalisation), Cardiogenic shock (na - Unknown - Caused/Not Specified Hospitalisation, Other Medically Important Condition), Chest pain (na - Unknown - Caused/Not Specified Hospitalisation), Death (na - Fatal - Results in Death), Dyspnoea (na - Unknown - Caused/Not Specified Hospitalisation), Hypoxia (na - Unknown - Caused/Not Specified Hospitalisation, Other Medically Important Condition), Jaundice (na - Unknown - Caused/Not Specified Hospitalisation), Multiple organ dysfunction syndrome (na - Unknown - Caused/Not Specified Hospitalisation, Other Medically Important Condition), Pneumonia (na - Unknown - Caused/Not Specified Hospitalisation, Other Medically Important Condition), Pyrrolis (na - Unknown - Caused/Not Specified Hospitalisation), Respiratory failure (na - Unknown - Caused/Not Specified Hospitalisation, Other Medically Important Condition), Tachypnoea (na - Unknown - Caused/Not Specified Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - Intramuscular])	METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE B[P] (Na - Type 2 diabetes mellitus - na - [na - 1000mg - Oral])	CSR
EU-EC-1000975463	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Not Specified	Death (01 - Fatal - Results in Death), Dyspnoea (01 - Fatal - Results in Death), Fatigue (01 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [1d - na - na])	GLUCOPHAGE (C - na - na -)	CSR
EU-EC-1000977279	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (1d - Fatal - Results in Death), Myocardial infarction (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])		CSR
EU-EC-1000998979	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Adverse event (na - Unknown - Caused/Not Specified Hospitalisation), Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR
EU-EC-1000998791	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000998795	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - 10d] - na)		CSR
EU-EC-1000988476	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death), Fluid retention (na - Unknown -), Liver disorder (na - Unknown -), Malaria (na - Unknown -), Multiple organ dysfunction syndrome (na - Unknown - Other Medically Important Condition), Pyrrolis (na - Unknown - Other Medically Important Condition), Thrombosis (na - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])		CSR
EU-EC-1000995482	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	Not Specified	Agitation (na - Unknown - Other Medically Important Condition), Aortic stenosis (na - Unknown - Other Medically Important Condition), Cerebral ischaemia (na - Fatal - Results in Death), Cardio-respiratory arrest (na - Fatal - Results in Death), Death (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation), Depressed level of consciousness (na - Unknown - Life Threatening, Caused/Not Specified Hospitalisation), Gaze palsy (na - Unknown - Life Threatening, Caused/Not Specified Hospitalisation), Oxygen saturation decreased (na - Unknown - Life Threatening, Caused/Not Specified Hospitalisation), Pyrrolis (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 3mL - Intramuscular])	BISOPROLOL FUMARATE (C - na - na - [na - 10d] - na), FURSEMIDE (C - na - na - [na - 10d] - na), LANSOPRAZOLE (C - na - na - [na - 10d] - na), DIETHYLENE FUMARATE (C - na - na - [na - 10d] - na), BISPRONOLACTONE (C - na - na - [na - 10d] - na), SUVOXRANE (C - na - na - [na - 10d] - na), NIFEDIPINE POTASSIUM (C - na - na - [na - 10d] - na)	CSR
EU-EC-1000996375	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - 10d] - na)		CSR
EU-EC-1000996376	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000995980	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000995969	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000996391	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000996421	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000996403	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000996426	16/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Elderly	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000996413	16/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Not Specified	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [1d - 3mL - Intramuscular])		CSR
EU-EC-1000994915	08/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000995039	08/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR
EU-EC-1000995317	08/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - 10d] - Intramuscular)		CSR
EU-EC-1000995924	08/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition), Ischaemic stroke (na - Fatal - Results in Death, Caused/Not Specified Hospitalisation, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])		CSR
EU-EC-1000995001	08/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000993165	08/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Cardiac arrest (na - Fatal - Results in Death), Death (na - Fatal - Results in Death), Dyspnoea (na - Unknown - Caused/Not Specified Hospitalisation), Respiratory tract infection (na - Unknown - Caused/Not Specified Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - na - na - [1d - na - na])		CSR
EU-EC-1000993769	08/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - Unknown])		CSR
EU-EC-1000993765	08/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Anxiety (01 - Fatal - Results in Death), Asthma (01 - Fatal - Results in Death), Asthma (01 - Fatal - Results in Death), Coordination abnormal (1d - Fatal - Results in Death), Death (na - Fatal - Results in Death), Nausea (01 - Fatal - Results in Death)	COMIRNATY COVID-19 mRNA VACCINE (NUCLEOSIDE MODIFIED) (TOZINAMERAN) (S - COVID-19 - na - [na - na - na])		CSR
EU-EC-1000993687	08/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - Unknown])		CSR
EU-EC-1000993621	08/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - Unknown])		CSR
EU-EC-1000994137	08/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death), Malaria (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])		CSR
EU-EC-1000991948	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	Not Specified	Death (01 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 3mL - Intramuscular])	ACEITYLSALICYLIC ACID (C - na - na - [na - 100mg - Oral]), FLUCONAZOLE (C - na - na -), GLYCERYL TRINERATE (C - na - na - [na - na - Transdermal]), METOPROLOL, METOPROLOL TARTRATE (C - na - na - [na - na - Oral]), PENTAPHYLME (C - na - na -), BISPRONOLACTONE (C - na - na - [na - na - Oral])	CSR
EU-EC-1000991961	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Not Specified	Death (01 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [na - 3mL - Intramuscular])		CSR
EU-EC-1000992070	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000992136	07/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY COVID-19 mRNA VACCINE (NUCLEOSIDE MODIFIED) (TOZINAMERAN) (S - COVID-19 - na - [na - na - na])		CSR
EU-EC-1000992141	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death), Herpes zoster (na - Unknown -), Herpetic lung disease (na - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000992890	07/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (na - Fatal - Results in Death), Chest pain (na - Not Recovered/Not Resolved -), Headache (na - Not Recovered/Not Resolved -), Malaria (na - Not Recovered/Not Resolved -), Myopia (na - Not Recovered/Not Resolved -), Nausea (na - Not Recovered/Not Resolved -), Tachycardia (na - Not Recovered/Not Resolved -), Vomiting (na - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000992265	07/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000992858	07/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (na - Fatal - Results in Death), Parkinson's disease (na - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - na - [na - na - na])		CSR
EU-EC-1000992135	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Not Specified	Death (01 - Fatal - Results in Death, Caused/Not Specified Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 3mL - Intramuscular])	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM BESILATE) (C - na - na -), TOLAZAR (TOLAZARIN) (C - na - na -), AMLODIPINE, AMLODIPINE HYDROCHLORIDE (C - na - na -), BISOPROLOL FUMARATE, BISOPROLOL FUMARATE PH. EUR., BISOPROLOL HEMIFUMARATE (C - na - na -), METFORMIN HYDROCHLORIDE (C - na - na -)	CSR
EU-EC-1000992219	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Not Specified	Coronary artery thrombosis (na - Fatal - Results in Death, Other Medically Important Condition), Death (01 - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (na - Fatal - Results in Death, Other Medically Important Condition), Pulse absent (01 - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - 10d] - Intramuscular)	EXORGINE (VALSARTAN, ALOSARTAN, VALSARTAN, ALOSARTAN BESILATE) (C - Hypertension - na - [na - na - na]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Hyperlipidaemia - na - [na - na - na])	CSR
EU-EC-1000992662	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Not Specified	Death (01 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 3mL - Intramuscular])		CSR
EU-EC-100099													

EU Local Number	EV Entry Reference Date	Report Type	Primary Country Qualification	Primary Country Regulatory Reference	Literature Reference	Patient Age Group	Patient Sex	Patient Race	Parent Drug	Reaction List PT (Duration / Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Class - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/ Administered Drug List (Drug Class - Indication PT - Action taken - Duration - Dose - Route)	CR Form	
EU-EC-100073036	24/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	TELICOLIBEROL (C - Intra - Intra - Intra - Intra)	CR18	
EU-EC-100073018	24/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	Not Specified	Female	Not Specified	No	COVID-19 (In - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100073024	23/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (In - Fatal - Results in Death)	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18
EU-EC-100073073	23/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100073066	23/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	Cardiovascular disorder (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cerebrovascular accident (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Coagulopathy (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Neurological disorder (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100074281	20/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Male	Not Specified	No	Asthma (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (In - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Weight decreased (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100074215	20/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	12-17 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100074214	20/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Male	Not Specified	No	Angina pectoris (In - Unknown - Other Medically Important Condition), Death (In - Fatal - Results in Death), Heart rate increased (In - Unknown -), Local reaction (In - Unknown -), Toxic shock syndrome (In - Unknown - Other Medically Important Condition)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100074212	20/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Female	Not Specified	No	COVID-19 (In - Unknown - Other Medically Important Condition), Cough (In - Unknown -), Death (In - Fatal - Results in Death), Drug ineffective (In - Unknown - Other Medically Important Condition), Fall (In - Unknown -), Oropharyngeal pain (In - Unknown -), Pain (In - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	ALLIPURMOLOL (C - Intra - Intra - Intra - Intra), ENALAPRIL MALEATE, ENALAPRILATE (C - Intra - Intra - Intra - Intra), HYDROCHLOROTHIAZIDE (C - Intra - Intra - Intra - Intra), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Intra - Intra - Intra - Intra), METFORMIN, METFORMIN HYDROCHLORIDE (C - Intra - Intra - Intra - Intra), PARACETAMOL (C - Intra - Intra - Intra - Intra), SRMSTATIN (C - Intra - Intra - Intra - Intra), TRAMADOL, HYDROCHLORIDE (C - Intra - Intra - Intra - Intra)	CR18	
EU-EC-100074211	20/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death), Diarrhoea (In - Unknown - Caused/Prolonged Hospitalisation), Vomiting (In - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100074205	20/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	Not Specified	Male	Not Specified	No	Death (In - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100074203	20/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Male	Not Specified	No	Anaesthesia (In - Unknown -), Anaphylactic reaction (In - Unknown - Other Medically Important Condition), Death (In - Fatal - Results in Death), Encephalopathy (In - Unknown - Other Medically Important Condition), Fibrile convulsion (In - Unknown -), Pyrexia (In - Unknown -), Septic (In - Unknown - Other Medically Important Condition), Thrombocytopenia (In - Unknown - Other Medically Important Condition), Toxic shock syndrome (In - Unknown - Other Medically Important Condition)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100074201	20/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Male	Not Specified	No	Asthma (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (In - Fatal - Results in Death), Dyspnoea (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100073203	19/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	Not Specified	Female	Not Specified	No	Death (In - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100073201	19/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Male	Not Specified	No	Acute kidney injury (In - Fatal - Results in Death), Brain death (In - Fatal - Results in Death), Brain oedema (In - Fatal - Results in Death), C-reactive protein increased (In - Fatal - Results in Death), Cerebral haemorrhage (In - Fatal - Results in Death), Cerebral ischaemia (In - Fatal - Results in Death), Cerebrovascular accident (In - Fatal - Results in Death), Coma (In - Fatal - Results in Death), Death (In - Fatal - Results in Death), Depressed level of consciousness (In - Fatal - Results in Death), Diarrhoea (In - Fatal - Results in Death), Endocarditis (In - Fatal - Results in Death), Haemorrhagic transformation stroke (In - Fatal - Results in Death), Hemiparesis (In - Fatal - Results in Death), Hypoxia (In - Fatal - Results in Death), Massive haemorrhage (In - Fatal - Results in Death), Mucositis (In - Fatal - Results in Death), Oxygen saturation decreased (In - Fatal - Results in Death), Pupils unequal (In - Fatal - Results in Death), Pyrexia (In - Fatal - Results in Death), Respiratory failure (In - Fatal - Results in Death), Septic shock (In - Fatal - Results in Death), Thrombocytopenia (In - Fatal - Results in Death), Vomiting (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	SIMPON (SOLAMERAN) (C - Intra - Unknown - Intra - 50mg - Intra), FOLIC ACID (C - Intra - Intra -), INFLORICAM (C - Intra - Unknown - Intra - 10mg - Intra), METHOTREXATE, METHOTREXATE SODIUM, METHOTREXATE SODIUM (C - Intra - Unknown - Intra - Intra - Intra), PANTOPRAZOLE, PANTOPRAZOLE SODIUM, SESQUIHYDRATE (C - Intra - Unknown - Intra - 150mg - Intra)	CR18	
EU-EC-100073202	19/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	Anaemia (In - Unknown -), Arrhythmia (In - Unknown - Other Medically Important Condition), Blood alkaline phosphatase decreased (In - Unknown -), Blood creatinine decreased (In - Unknown -), Blood thyroid stimulating hormone decreased (In - Unknown -), C-reactive protein increased (In - Unknown -), Cardiac failure (In - Unknown - Other Medically Important Condition), Cardiomegaly (In - Unknown -), Cardiothoracic ratio increased (In - Unknown -), Death (In - Fatal - Results in Death), Diarrhoea (In - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (In - Unknown -), Gas disturbance (In - Unknown - Caused/Prolonged Hospitalisation), Haematocrit decreased (In - Unknown -), Haemoglobin decreased (In - Unknown -), Lymphocyte count decreased (In - Unknown -), Malaise (In - Unknown -), Mean cell haemoglobin concentration decreased (In - Unknown -), Mean cell volume decreased (In - Unknown -), Neutrophils (In - Unknown - Caused/Prolonged Hospitalisation), Orthopnea (In - Unknown -), Pulser (In - Unknown -), Red blood cell count decreased (In - Unknown -), Reticulocyte count decreased (In - Unknown -), Ventricular failure (In - Unknown - Other Medically Important Condition), Vomiting (In - Unknown - Caused/Prolonged Hospitalisation), White blood cell count decreased (In - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	AMODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Intra - Intra - Intra - Intra), ENALAPRIL, ENALAPRIL MALEATE (C - Intra - Intra - Intra - Intra), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Intra - Intra - Intra - Intra), OMEPRAZOLE (C - Intra - Intra - Intra - Intra), SRMSTATIN (C - Intra - Intra - Intra - Intra), WARFARIN, WARFARIN SODIUM (C - Intra - Intra - Intra - Intra)	CR18	
EU-EC-100073405	19/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death), Death (In - Fatal - Results in Death, COVID-19 - Not Recovered/Not Resolved -)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100073404	19/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	COVID-19 (In - Fatal - Results in Death), Cardio-respiratory arrest (In - Fatal - Results in Death), Death (In - Fatal - Results in Death), Vaccination failure (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100073370	19/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	CYMBALTA (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Depression - Intra - Intra - Intra - Intra), BUPROPRION, BUPROPRION SODIUM (C - Headache - Intra - Intra - Intra - Intra), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Thrombolysis prophylaxis - Intra - Intra - 75mg - Oral), ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE (C - Osteoporosis - Intra - Intra - 70mg - Oral), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Hypercholesterolemia - Intra - Intra - 40mg - Oral), CODICINE PHOSPHATE SESQUIHYDRATE (C - Headache - Intra - Intra - 25mg - Oral), CYNOCALZEM (C - Vasomotor rhinitis - Intra - Intra - 1mg - Oral), DIBENZO (DIBENZO MALEATE, FENICONE SULFATE) (C - Non-dependent - Intra - Intra - 100mg - Oral), ENALAPRIL MALEATE (C - Hypertension - Intra - Intra - 5mg - Oral), PANTOPRAZOLE, PANTOPRAZOLE SODIUM, SESQUIHYDRATE (C - Gastroesophageal reflux disease - Intra - Intra - 40mg - Oral), POTASSIUM CHLORIDE (C - Mineral supplementation - Intra - Intra - 1500mg - Oral), QUETIAPINE, QUETIAPINE FUMARATE, QUETIAPINE HEMIUMARATE (C - Depression - Intra - Intra - 100mg - Oral), TERBUTALINE SULFATE (C - Bronchospasm - Intra - Intra - 5mg - Respiratory inhalation)	Not reported	CR18
EU-EC-100073033	19/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100073031	19/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Female	Not Specified	No	Circulatory collapse (In - Not Recovered/Not Resolved - Other Medically Important Condition), Death (In - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100073028	19/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Female	Not Specified	No	Choking (In - Unknown - Other Medically Important Condition), Death (In - Fatal - Results in Death), Diarrhoea (In - Unknown -), Speech disorder (In - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100072230	18/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100072493	19/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Male	Not Specified	No	Aphasia (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), C-reactive protein increased (In - Unknown -), Coordination abnormal (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Dysarthria (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Encephalopathy viral (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Epilepsy (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Genitourinary tract infection (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiparesis (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Myalgia (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pyrexia (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Somnolence (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), White blood cell count increased (In - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	APIXABAN (APIXABAN) (C - Embolic venous, Pneumonia - Intra - Intra - Intra), BIMATOROST (BIMATOROST) (C - Glaucoma - Intra - Intra - Intra), LEVETIRACETAM (LEVETIRACETAM) (C - Epilepsy - Intra - Intra - Intra), SINNA (SINNOSSIDE A+B) (SINNOSSIDE A+B) (C - Constipation - Intra - Intra - Intra), ADICOLIN, ACICLOVIR SODIUM (C - Encephalitis - Intra - Intra - Intra), ALLIPURMOLOL (C - Oral - Intra - Intra - Intra), AMOXICILIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILIN, CLAVULANIC ACID, AMOXICILIN, POTASSIUM CLAVULANATE (C - Aspiration - Intra - Intra - Intra), CEFTRIAXONE, CEFTRIAXONE SODIUM (C - Encephalitis - Intra - Intra - Intra), DORZOLAMIDE HYDROCHLORIDE, TIMOLOL, DORZOLAMIDE HYDROCHLORIDE, TIMOLOL MALEATE, DORZOLAMIDE, TIMOLOL (C - Glaucoma - Intra - Intra - Intra), FOLIC ACID (C - Intra - Intra - Intra - Intra), LANOPRAZOLE (C - Abdominal pain, Gastroesophageal reflux disease - Intra - Intra - Intra), LATANOPROST (C - Intra - Intra - Intra - Intra), LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE (C - Intra - Intra - Intra - Intra), LOSARTAN, LOSARTAN POTASSIUM (C - Hypertension - Intra - Intra - Intra), MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350 (C - Constipation - Intra - Intra - Intra), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIPHENYL (C - Diabetes mellitus - Intra - Intra - Intra), MORFININE SULFATE, MORFININE SULFATE BIPHENYL (C - Pain - Intra - Intra - Intra - Intra), NORFINANE, MORFINANE HYDROCHLORIDE (C - Pain - Intra - Intra - Intra - Intra), PARACETAMOL (C - Pain - Intra - Intra - Intra - Intra), SODIUM HYALURONATE (C - Glaucoma - Intra - Intra - Intra - Intra)	CR18	
EU-EC-100073246	17/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death, Other Medically Important Condition), Fungal (In - Recovered/Resolved -)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100073236	17/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Male	Not Specified	No	Acute myocardial infarction (In - Unknown - Life Threatening, Other Medically Important Condition), Aphasia (In - Unknown - Other Medically Important Condition), Cardiac infarction (In - Unknown - Life Threatening, Other Medically Important Condition), Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100073035	17/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Female	Not Specified	No	Cerebrovascular accident (In - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100073027	17/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Adult	Female	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100073033	17/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100073010	17/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (In - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100073079	17/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Elderly	Male	No	Death (In - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Language disorder (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paralysis (In - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMPRNATY (TOZINAMERAN) (S - Immunosuppression - Intra - Intra - Intra)	Not reported	CR18	
EU-EC-100069590	16/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Female	Not Specified	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	Not reported	CR18	
EU-EC-100069594	16/09/2021	Sponaneous	Non-Healthcare Professional	Non-Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100069590	16/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100069597	16/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	18-64 Years	Adult	Male	No	Cardio-respiratory arrest (In - Fatal - Results in Death), Death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [1d - Intra - Intra])	Not reported	CR18	
EU-EC-100067426	13/09/2021	Sponaneous	Healthcare Professional	Non-Economic Area	Not available	More than 95 Years	Male	Not Specified	No	Death (In - Fatal - Results in Death), Sudden death (In - Fatal - Results in Death)	COMPRNATY (TOZINAMERAN) (S - COVID-19 immunosuppression - Not applicable - [In - Intra - Intra])	CALCIOTRICAL (C - Intra - Intra - Intra - Intra), CANRENONE, POTASSIUM CANRENONE (C - Intra - Intra - Intra - Intra), FINASTERIDE (C - Intra - Intra - Intra - Intra), FOLIC ACID (C - Intra - Intra - Intra - Intra), FLUOREMIDE (C - Intra - Intra - Intra - Intra), OMEPRAZOLE (C - Intra - Intra - Intra - Intra)	CR18	

EU Local Number	EV Entry/Revise Date	Report Type	Primary Country	Primary Country Regulatory Reference	Literature Reference	Patent (EU)	Patent (EU) (per report)	Patent (EU) (per report)	Patent (EU) (per report)	Reaction List (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)	CSR Form	
EU-EC-100067014	13/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Asthma (14 - Fatal - Results in Death), Cardio-respiratory arrest (19 - Fatal - Results in Death), Death (19 - Fatal - Results in Death), Foggy (14 - Fatal - Results in Death), Mekle (14 - Fatal - Results in Death), Pulmonary pain (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19 - 19] - [19])	Not reported	C18	
EU-EC-100067042	13/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebral haemorrhage (20 - Fatal - Results in Death), Death (20 - Fatal - Results in Death), Nervous system disorder (20 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19 - 19] - [19])	JANVIA (SITAGLUPFIN, SITAGLUPFIN PHOSPHATE, SITAGLUPFIN PHOSPHATE MONOHYDRATE) (C - 19 - Unknown - [19 - 19] - [19]), LANTUS (INSULIN GLARGINE) (C - 19 - Unknown - [19 - 19] - [19]), NETFORMAN (METFORMIN HYDROCHLORIDE) (C - 19 - Unknown - [19 - 19] - [19]), ROSELVASTATIN (ROSELVASTATIN CALCIUM) (C - 19 - Unknown - [19 - 19] - [19])	C18	
EU-EC-100067141	13/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-100067796	13/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aortic dissection (21 - Fatal - Results in Death), Back pain (21 - Fatal - Results in Death), Cardiovascular disorder (21 - Fatal - Results in Death), Death (19 - Fatal - Results in Death), Diplopia (14 - Fatal - Results in Death), Dyspnoea (21 - Fatal - Results in Death), Mekle (21 - Fatal - Results in Death), Monoplegia (14 - Fatal - Results in Death), Renal failure (21 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19 - 19] - [19])	Not reported	C18	
EU-EC-1000678473	13/03/2021	Sponsorless	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cerebrovascular accident (14 - Recovered/Resolved - Caused/Prolonged Hospitalisation, Dying), Cerebrovascular accident (19 - Unknown - Caused/Prolonged Hospitalisation, Dying), Death (19 - Fatal - Results in Death)	(TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 19] - [19] - [19])	DIKAZONEN, DOXAZONEN MESILATE (C - 19 - Unknown - [19 - 19] - [19]), DUTASTERIDE (C - 19 - Unknown - [19 - 19] - [19]), EMERIZON (C - 19 - Unknown - [19 - 19] - [19]), PANTOPRAZOLE SODIUM (C - 19 - Unknown - [19 - 19] - [19]), TICLOPIDINE (C - 19 - Unknown - [19 - 19] - [19])	C18	
EU-EC-100067913	13/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COVID-19 (174 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory distress (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19 - 19] - [19])	ALLOPURINOL (C - 19 - Unknown - [19 - 19] - [19]), METOPROLOL TARTRATE, METOPROLOL TARTRATE BP (C - 19 - Unknown - [19 - 19] - [19]), MOLSIDOMINE (C - 19 - Unknown - [19 - 19] - [19]), OPIPRACOLE, OPIPRACOLE MAGNESIUM OPIPRACOLE SODIUM (C - 19 - Unknown - [19 - 19] - [19]), SEMESTATIN (C - 19 - Unknown - [19 - 19] - [19]), FAMBUSOLEN, FAMBUSOLEN HYDROCHLORIDE (C - 19 - Unknown - [19 - 19] - [19]), TICLOPIDINE HYDROCHLORIDE (C - 19 - Unknown - [19 - 19] - [19])	C18	
EU-EC-100068070	13/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Aortic rupture (19 - Fatal - Results in Death), Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19 - 19] - [19])	Not reported	C18	
EU-EC-100068196	13/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (19 - Fatal - Results in Death), Pulmonary embolism (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-100069172	12/03/2021	Sponsorless	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Circulatory collapse (19 - Fatal - Results in Death, Other Medically Important Condition), Death (19 - Fatal - Results in Death, Other Medically Important Condition), Syncope (19 - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-100069538	12/03/2021	Sponsorless	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal pain (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (19 - Fatal - Results in Death), Intestinal obstruction (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-100069549	12/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Flu (19 - Fatal - Results in Death), Flu (19 - Fatal - Results in Death), Leukocytosis (15 - Fatal - Results in Death), Neutrophilia (15 - Fatal - Results in Death), Oxygen saturation decreased (14 - Fatal - Results in Death), Pulmonary embolism (19 - Fatal - Results in Death), Thrombocytopenia (14 - Fatal - Results in Death), Urinary tract infection (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19 - 19] - [19])	BROMAZEPAM (C - 19 - Unknown - [19 - 19] - [19]), CALCIUM CARBONATE, CHOLECALCIFEROL, CONCENTRATE (POWDER FORM) (C - 19 - Unknown - [19 - 19] - [19]), FDIC ACID (C - 19 - Unknown - [19 - 19] - [19]), PARACETAMOL, PARACETAMOL CODICONE PHOSPHATE HEMIHYDRATE (C - 19 - Unknown - [19 - 19] - [19])	C18	
EU-EC-1000696470	12/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19 - 19] - [19])	Not reported	C18	
EU-EC-100069893	12/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Female	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000699447	12/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (19 - Fatal - Results in Death), Dyspnoea (19 - Fatal - Results in Death), Musculoskeletal disorder (19 - Fatal - Results in Death), Pyrexia (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - 19 - 19 - [19] - [19])	Not reported	C18	
EU-EC-1000699523	12/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000699598	11/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (97 - Fatal - Results in Death), Death (19 - Fatal - Results in Death), Cardiac arrest (21 - Fatal - Results in Death), Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000699577	11/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	(ACETYSALICYLIC ACID) (C - 19 - Unknown - [19]), NEBIVOLOL (C - 19 - Unknown - [19]), OLMESARTAN MEDOXOMIL, AMLDOPRINE (C - 19 - Unknown - [19]), SEMESTATIN (C - 19 - Unknown - [19])	C18	
EU-EC-1000699317	10/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000698441	10/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (19 - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (12 - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000698468	10/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (19 - Unknown - Other Medically Important Condition), Cardiac failure (19 - Unknown - Other Medically Important Condition), Death (19 - Fatal - Results in Death), Drug ineffective (19 - Unknown - Other Medically Important Condition), Lower respiratory tract infection (19 - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000694962	10/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	Measles (19 - Unknown - [19])	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000694270	10/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Male	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000695285	09/03/2021	Sponsorless	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 pneumonia (19 - Unknown - Caused/Prolonged Hospitalisation), Death (19 - Fatal - Results in Death), Dyspnoea (19 - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000695024	09/03/2021	Sponsorless	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Brucellosis (19 - Unknown - [19]), Dyspnoea (19 - Unknown - [19]), Fall (19 - Unknown - Other Medically Important Condition), Hypoxic-ischaemic encephalopathy (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (19 - Fatal - Results in Death), Near drowning (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory arrest (19 - Fatal - Results in Death), Skin lesion (19 - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000695266	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	Death (19 - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	TELSARTAN BI MO (C - 19 - Unknown - [19] - 80mg - [19]), ALLOPURINOL (C - 19 - Unknown - [19]), ALLOPURINOL (C - 19 - Unknown - [19] - [19] - [19]), ALPHA-TOCOPHEROL (C - 19 - Unknown - [19] - [19] - [19]), ASCORBIC ACID (C - 19 - Unknown - [19] - [19] - [19]), ATORVASTATIN, ATORVASTATIN CALCIUM (C - 19 - Unknown - [19] - 20mg - [19]), AZATHIOPRINE, AZATHIOPRINE BP, AZATHIOPRINE PH. EUR. (C - 19 - Unknown - [19] - [19] - [19]), AZATHIOPRINE (C - 19 - Unknown - [19] - [19] - [19]), DOXICALCIPEROL (C - 19 - Unknown - [19] - [19] - [19]), FURSEMIDE (C - 19 - Unknown - [19] - [19] - [19]), GLUCOCORTIC (C - 19 - Unknown - [19]), GLYCOE, ACETYSALICYLIC ACID (C - 19 - Unknown - [19] - [19] - [19]), LERCANIDIPINE HYDROCHLORIDE (C - 19 - Unknown - [19] - [19] - [19]), MICRONISED PURIFIED FLAVONIC FRACTION (C - 19 - Unknown - [19] - [19] - [19]), PYRIDOXINE HYDROCHLORIDE, VITAMIN B6 (C - 19 - Unknown - [19] - [19] - [19]), PRIMIDONE (C - 19 - Unknown - [19] - [19] - [19]), TELMILOSARTAN (C - 19 - Unknown - [19])	C18	
EU-EC-1000697811	09/03/2021	Sponsorless	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (19 - Fatal - Results in Death), Hypokalaemia (19 - Unknown - Other Medically Important Condition), Pyrexia (19 - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	BACILLUS SUBTILIS, LACTON, BIFIDOBACTERIA (C - 19 - Unknown - [19] - [19] - [19]), CLOSTRIDIUM BUTYRICUM (C - 19 - Unknown - [19] - [19] - [19]), ELDECALCITRIOL (C - 19 - Unknown - [19] - [19] - [19]), GALANTAMINE HYDROBROMIDE (C - 19 - Unknown - [19] - [19] - [19]), HYDROXYMETHYLGLUCOSYL-GLUCOSIDES, SPINDRIDES (C - 19 - Unknown - [19] - [19] - [19]), LANSOPRAZOLE (C - 19 - Unknown - [19] - [19] - [19]), PARACETAMOL (C - 19 - Unknown - [19] - [19] - [19]), POTASSIUM ASPARTATE, POTASSIUM L-ASPARTATE (C - 19 - Unknown - [19] - [19] - [19]), URSODIOLIC ACID (C - 19 - Unknown - [19] - [19] - [19])	C18	
EU-EC-1000692648	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	Arthralgia (19 - Unknown - [19]), Death (19 - Fatal - Results in Death), Rash (19 - Unknown - [19])	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000692617	09/03/2021	Sponsorless	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute respiratory distress syndrome (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bronchospasm (19 - Unknown - Caused/Prolonged Hospitalisation), Chills (19 - Unknown - Caused/Prolonged Hospitalisation), Cough (19 - Unknown - Caused/Prolonged Hospitalisation), Cyanosis (19 - Unknown - Caused/Prolonged Hospitalisation), Death (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Depressed level of consciousness (19 - Unknown - Caused/Prolonged Hospitalisation), Dermoses (19 - Unknown - Caused/Prolonged Hospitalisation), Diffuse alveolar damage (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (19 - Unknown - Caused/Prolonged Hospitalisation), Erythema (19 - Unknown - Caused/Prolonged Hospitalisation), Fatigue (19 - Unknown - Caused/Prolonged Hospitalisation), Headache (19 - Unknown - Caused/Prolonged Hospitalisation), Hypotension (19 - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (19 - Unknown - Caused/Prolonged Hospitalisation), Mekle (19 - Unknown - Caused/Prolonged Hospitalisation), Myalgia (19 - Unknown - Caused/Prolonged Hospitalisation), Oncopharyngeal pain (19 - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (19 - Unknown - Caused/Prolonged Hospitalisation), Rash (19 - Unknown - Caused/Prolonged Hospitalisation), Respiratory distress (19 - Unknown - Caused/Prolonged Hospitalisation), Serous skin (19 - Unknown - Caused/Prolonged Hospitalisation), Septic (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Shock (19 - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (19 - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (19 - Unknown - Caused/Prolonged Hospitalisation), Wheezing (19 - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000693121	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Female	Death (19 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (19 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (19 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (19 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (19 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site haemorrhage (19 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000693172	09/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [20] - [20] - [19])	DIABETALAN (DIABETALAN) (C - 19 - [19] - [19]), IBUFEN (IBUFEN) (C - 19 - [19] - [19])	Not reported	C18
EU-EC-1000693303	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Monoplegia (19 - Fatal - Results in Death), Pain in extremity (19 - Not Recovered/Not Resolved - [19]), Vaccination site haemorrhage (19 - Not Recovered/Not Resolved - [19]), Vaccination site nodules (19 - Not Recovered/Not Resolved - [19]), Vaccination site scar (19 - Not Recovered/Not Resolved - [19])	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000693499	09/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000691976	09/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	C-reactive protein increased (14) - Fatal - Results in Death), Death (14) - Fatal - Results in Death), General physical health deterioration (14) - Fatal - Results in Death), Inflammation (14) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	LIQVIA (DOBAMAN, EDOKAVAN TOSYLATE) (C - 19 - Unknown - [19] - [19] - [19]), ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY MAGNESIUM (C - 19 - Unknown - [19] - [19] - [19]), BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL, HEMIFUMARATE (C - 19 - Unknown - [19] - [19] - [19]), CALCIUM CITRATE (C - 19 - Unknown - [19] - [19] - [19]), DOXICALCIPEROL (C - 19 - Unknown - [19] - [19] - [19]), DUCON, DUCONIN ELIX (C - 19 - Unknown - [19] - [19] - [19]), DOPENZOLIN (C - 19 - Unknown - [19] - [19] - [19]), HALOPERIDOL, HALOPERIDOL DECANOATE (C - 19 - Unknown - [19] - [19] - [19]), QUETIAPINE, QUETIAPINE FUMARATE (C - 19 - Unknown - [19] - [19] - [19])	C18	
EU-EC-1000691242	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	Death (19 - Fatal - Results in Death), Chest pain syndrome (19 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000691439	09/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000691596	09/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	Death (19 - Fatal - Results in Death), Headache (19 - Recovered/Resolved - [19]), Mekle (19 - Recovered/Resolved - [19])	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - [19 - 19] - [19] - [19])	Not reported	C18	
EU-EC-1000691673	09/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	Death (19 - Fatal - Results in Death), Pretympania (19 - Recovered/Resolved - [19])	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	NETFORMAN, NETFORMAN HYDROCHLORIDE (C - 19 - Unknown - [19] - [19] - [19])	C18	
EU-EC-1000691972	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (19 - Fatal - Results in Death, Other Medically Important Condition), Hemorrhoid (19 - Unknown - Other Medically Important Condition), Menstrual irregularities (19 - Unknown - Other Medically Important Condition), Nausea (19 - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000692060	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Corn (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000692079	09/03/2021	Sponsorless	Non-Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	Not reported	C18	
EU-EC-1000692667	09/03/2021	Sponsorless	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (19 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [19] - [19] - [19])	BUPRENORPHINE, MELoxicam (C - Rheumatoid arthritis - [19] - [19] - [19] - [19]), METHOTREXATE (C - Rheumatoid arthritis - [19] - [19] - [19] - [19]), METHYLPREDNISOLONE (C - Rheumatoid arthritis - [19] - [19] - [19] - [19])	C18	

EU Local Number	EV Summary Review Date	Report Type	Primary Country	Primary Country Regulatory Authority	Literature Reference	Patent Age Group	Patent (as per sponsor)	Patent Sex	Patent DM1 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])	CSR Form
EU-EC-100094339	21/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Seizure (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved/Not Reported - Other Medically Important Condition), Syncope (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved/Not Reported - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	CSR
EU-EC-100094381	20/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Arrhythmia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	ZYPREXA (OLANZAPINE) (C - n/a - n/a - [n/a - n/a - Oral]), BIPHENACOL HYDROCHLORIDE, BIPHENACOL LACTATE (C - n/a - n/a - [n/a - n/a - Oral]), DICLOFENAC (C - n/a - n/a - [n/a - n/a - Oral]), FLOTANOL (C - n/a - n/a - [n/a - n/a - Oral]), FLOTANOL (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]), METOCLOPRAMIDE (C - n/a - n/a - [n/a - n/a - Oral]), NIBOXANE (C - n/a - n/a - [n/a - n/a - Oral])	CSR
EU-EC-100094377	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-100094201	20/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Cardiac arrest (n/a - Fatal - Results in Death), Chronic obstructive pulmonary disease (n/a - Recovered/Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Wheezing (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	RESPIR ELLIPTA FLUTICASON FURATE, VALNERTOL (C - n/a - n/a - [n/a - n/a - Respiratory Inhalation]), MAGNESIUM OXIDE (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-100094054	18/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Back disorder (n/a - Unknown - Caused/Not Resolved/Not Reported - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dysphasia (n/a - Unknown - Caused/Not Resolved/Not Reported - Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-100094017	18/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Arrhythmia (n/a - Unknown -), Asthma (n/a - Unknown -), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Epilepsy (n/a - Unknown -), Fatigue (n/a - Unknown -), Hypertension (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	APIXARAN - FILM COATED TABLET (C - n/a - Not applicable -), ALLORPINOLOL (C - n/a - Not applicable -), ZOPICLONE (C - n/a - Not applicable -)	CSR
EU-EC-100094017	18/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Hypertension (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ACETYSALICYLIC ACID (C - Myocardial infarction - n/a - [n/a - n/a - Oral])	CSR
EU-EC-100094009	18/07/2021	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 - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-100094026	16/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Not Resolved/Not Reported - Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	ACETYSALICYLIC ACID (C - n/a - n/a - [n/a - n/a - Oral]), AMIODARONE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), AMLODIPINE (C - n/a - n/a - [n/a - n/a - Oral]), ATORVASTATIN (C - n/a - n/a - [n/a - n/a - Oral]), FENOTEROL HYDROBROMIDE, IPRAATROPOL BROMIDE, FENOTEROL HYDROBROMIDE, IPRAATROPOL 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]), FENOFIBRIL (C - n/a - n/a - [n/a - n/a - Oral]), FLUOREMIDE (C - n/a - n/a - [n/a - n/a - Oral]), METOPROLOL TERZAPATE (C - n/a - n/a - [n/a - n/a - Oral]), METOPROLOLOL (C - n/a - n/a - [n/a - n/a - Oral]), SPINODOLACTONE (C - n/a - n/a - [n/a - n/a - Oral]), THEOPHYLLINE (C - n/a - n/a - [n/a - n/a - Oral]), TIPTROPOLM OLODATEROL (C - n/a - n/a - [n/a - n/a - Oral])	CSR
EU-EC-100093701	15/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-100093717	15/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-100093636	15/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Product used for uraemic indication - Not applicable - [n/a - 10DF] - Urinary), COVID-19 MRNA VACCINE MODERNA (CA-100414) (COVID-19 MRNA VACCINE MODERNA (CA-100414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-100093676	14/07/2021	Spontaneous	Healthcare Professional	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 - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - n/a)	CAPTOPRIL (C - Hypertension - n/a - [n/a - n/a - Oral])	CSR
EU-EC-100093613	14/07/2021	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/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - n/a)	Not reported	CSR
EU-EC-100093493	13/07/2021	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/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Oral])	Not reported	CSR
EU-EC-100093491	13/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Brain ganglia infection (n/a - Fatal - Results in Death), Cerebral endovascular aneurysm repair (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), Ventricular septal defect (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dementia Alzheimer's type (n/a - Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	CSR
EU-EC-100093226	13/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-100093205	13/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Purpura (n/a - Fatal - Results in Death), Rash macular (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Feeling abnormal (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-100093194	12/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-100093421	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	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	CSR
EU-EC-100093404	12/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Life Threatening), Product not used (n/a - Unknown -)	COVID-19 VACCINE AZTRAZENACA (CHAD0X1 NCOV-19) (COVID-19 VACCINE AZTRAZENACA (CHAD0X1 NCOV-19)) (S - Immunisation - Unknown - [1d - n/a - n/a]), (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	CSR
EU-EC-100093388	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-100093381	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [2d - n/a - Intramuscular])	RELTEK (RILUZOLEL) (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])	CSR
EU-EC-100093345	12/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	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), Pyrexia (n/a - Unknown - 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	CSR
EU-EC-100093343	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-100093300	12/07/2021	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 - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-100093416	12/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-100093115	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-100093100	08/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Foaming at mouth (n/a - Not Resolved/Not Reported - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Resolved/Not Reported - Other Medically Important Condition), Vomiting (n/a - Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-100093182	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-100093176	08/07/2021	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])	ACINOCOLMAMARIS (C - n/a - n/a - [n/a - n/a - Oral]), BISOPROLOL FUMARATE, BISOPROLOL FUMARATE, ACETYSALICYLIC ACID, BISOPROLOL, HEMIFUMARATE (C - n/a - n/a - [n/a - n/a - Oral]), VALSARTAN (C - n/a - n/a - [n/a - n/a - Oral])	CSR
EU-EC-100093141	08/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	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 -), Sinus dysrhythmia (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-100093124	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-100093125	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 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	CSR
EU-EC-100093186	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-100093207	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - Intramuscular)	ACETYSALICYLIC ACID, D,L-LYSINE ACETYSALICYLATE (C - n/a - n/a -), ALLORPINOLOL (C - n/a - n/a -), AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL (C - n/a - n/a -), FLUOREMIDE (C - n/a - n/a -), METFORMIN, METFORMIN HYDROCHLORIDE (C - n/a - n/a -), SODIUM POLYETHYLENE SULPHONATE (C - n/a - n/a -)	CSR
EU-EC-100093178	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 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	CSR
EU-EC-100093246	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 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	CSR
EU-EC-100093169	08/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Life Threatening, Caused/Not Resolved/Not Reported - 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/Not Resolved/Not Reported - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Muscle fatigue (n/a - Unknown -), Oedema peripheral (n/a - Unknown - Caused/Not Resolved/Not Reported - Other Medically Important Condition), Oedema peripheral (n/a - Unknown - Other Medically Important Condition), Cardiorespiratory (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Paroxysmal atrial fibrillation (n/a - Fatal - Results in Death), Lip swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Pain 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), Urinary (n/a - Recovered/Resolved -), 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)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10DF] - n/a)	Not reported	CSR
EU-EC-100093287	07/07/2021	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), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - n/a])	XARELTO (RISERVROXIBAN) (C - n/a - Not applicable -), ALLORPINOLOL (C - n/a - Not applicable -), BISOPROLOL FUMARATE, BISOPROLOL, HEMIFUMARATE (C - n/a - Not applicable -), DOHAZON, DOHAZON MESILATE (C - n/a - Not applicable -), METFORMIN HYDROCHLORIDE (C - n/a - Not applicable -), SPINODOLACTONE (C - n/a - Not applicable -), THEOPHYLLINE (C - n/a - Not applicable -), (TOZINAMERAN) (S - n/a - Not applicable -)	CSR
EU-EC-100093176	07/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Coronavirus (n/a - Not Resolved/Not Reported - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Maculohyalostasis (n/a - Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-100093265	07/07/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Facial asymmetry (n/a - Not Resolved/Not Reported - Other Medically Important Condition), Facial paresthesia (n/a - Not Resolved/Not Reported - Other Medically Important Condition), Foaming at mouth (n/a - Not Resolved/Not Reported - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 20DF] - n/a)	Not reported	CSR
EU-EC-100092770	06/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	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 (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	JANUVA (SITAGLUPFIN, SITAGLUPFIN PHOSPHATE, SITAGLUPFIN PHOSPHATE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - Oral]), LANTUS SOLESTAR (INSULIN GLARGINE) (C - n/a - n/a - [n/a - n/a - n/a]), ALLORPINOLOL (C - n/a - n/a - [n/a - n/a - Oral]), ACETYSALICYLIC ACID (C - n/a - n/a - [n/a - n/a - Oral]), ALUMINUM HYDROXIDE GEL, CHEDER, 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, SODIUM HYDROGEN CARBONATE GEL, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, SODIUM ALGINATE (C - n/a - n/a - [n/a - n/a - Oral]), (CARBAMAZEPINE) (C - n/a - n/a - [n/a - n/a - Oral]), (CARBAMAZEPINE) (C - n/a - n/a - [n/a - n/a - Oral]), (CARTERON) (C - n/a - n/a - [n/a - n/a - Oral]), (CALCIUM CARBONATE, CALCIUM GLUCONATE, CALCIUM GLUCONATE, CALCIUM CARBONATE) (C - n/a - n/a - [n/a - n/a - Oral]), (ESTROL) (C - n/a - n/a - [n/a - n/a - Vaginal]), (FENTANYL) (C - n/a - n/a - [n/a - n/a - Transdermal]), (FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL, XINAPATE) (C - n/a - n/a - [n/a - n/a - Respiratory Inhalation]), (FLUOREMIDE) (C - n/a - n/a - [n/a - n/a - Oral]),	CSR

EU Lead Number	EV Gateway Review Date	Report Type	Primary Country (Healthcare Professional)	Literature Reference	Primary Country (Regulatory Purpose)	Not available	Patent (EU/US)	Patent (JP)	Patent (Other)	Patent (Other)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspicious/Interacting Drug List (Drug Class - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Class - Indication PT - Action taken - [Duration - Dose - Route])	CER Form	
EU-EC-100009181	18/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CER	
EU-EC-100009238	18/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CER	
EU-EC-100009560	18/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-100009574	18/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1d - 10d] - Intramuscular)	Not reported	CER	
EU-EC-100009708	18/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 10d] - Intramuscular)	Not reported	CER	
EU-EC-100004761	17/06/2021	Spontaneous	Healthcare Professional	Not available	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac failure (n/a - Unknown - Caused/Not Caused/Not Reported), Chest pain (n/a - Unknown -), Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Myalgia (n/a - Unknown -), Pneumonia (n/a - Unknown -), Pulmonary congestion (n/a - Unknown - Caused/Not Caused/Not Reported), Pyrexia (n/a - Unknown -), Sinus tachycardia (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	CER	
EU-EC-100009147	17/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ADMUS (DESGLONATAMER) (C - n/a - n/a - [n/a - n/a - n/a]), ACETYLCYSTEINE, ACETYLCYSTEINE SODIUM (C - n/a - n/a - [n/a - n/a - n/a]), AMTIRYPTLINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), COLESIDONE (C - n/a - n/a - [n/a - n/a - n/a]), CLOBETASOL PROPIONATE (C - n/a - n/a -), DIOCALCOPROL (C - n/a - n/a -), CYMOCOBALAMIN, HYDROXYCOBALAMIN (C - n/a - n/a -), ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM ESOMEPRAZOLE TRIHYDRATE, ESOMEPRAZOLE SODIUM (C - n/a - n/a -), ESTERADOL, ESTERADOL HYDRATE (C - n/a - n/a -), NICOLINAM, PIRACETAM, PIRACETAM HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), METOCLOPRAMIDE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), DIYOCODONE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), PARAFRIN (C - n/a - n/a -), (SALURITAMOL, SALURITAMOL SULFATE) (C - n/a - n/a -), (SODIUM PHOSPHATE) (C - n/a - n/a -), (SALURITAMOL, SALURITAMOL SULFONATE) (C - n/a - n/a - [n/a - n/a - n/a]), (TERBUTALINE SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (DOPLOLON) (C - n/a - n/a - [n/a - n/a - n/a])	CER	
EU-EC-100009101	17/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000091815	17/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000091864	17/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000091865	17/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000092038	17/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000093219	16/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Chest pain (n/a - Fatal - Results in Death, Other Medically Important Condition), Coronary artery disease (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	LEVOTHYROXINE SODIUM (C - n/a - n/a - [n/a - n/a - n/a]), (SMRISTATIN) (C - n/a - n/a - [n/a - n/a - n/a])	CER	
EU-EC-1000093476	16/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000093093	16/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Sudden cardiac death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000093092	16/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CER	
EU-EC-1000093759	16/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CER	
EU-EC-1000093750	16/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	Not reported	CER	
EU-EC-1000093872	16/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000094545	16/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE 20 MG - COATED RESEALANT TABLET (C - n/a - n/a - [n/a - n/a - n/a]), PREGABALIN/PREGABALIN (C - n/a - n/a - [n/a - n/a - n/a]), (DUMARIN) (C - n/a - n/a - [n/a - n/a - n/a]), (SPRONOLACTONE) (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	CER
EU-EC-1000041167	16/06/2021	Spontaneous	Non-Healthcare Professional	Not available	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Lactic acidosis (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Caused/Not Caused/Not Reported)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CER	
EU-EC-10000921474	15/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000092036	15/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000092146	15/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Breast (n/a - Fatal - Results in Death), Somnolence (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	FURIOEMIDE, FURIOEMIDE SODIUM (C - n/a - Unknown - [n/a - n/a - n/a])	CER	
EU-EC-1000092347	15/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (n/a - Fatal - Results in Death), Corns (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Haemorrhage (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CER	
EU-EC-1000092453	15/06/2021	Spontaneous	Healthcare Professional	Not available	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cardiac arrest (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)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	(ACETYLSALICYLIC ACID) (C - n/a - n/a - [n/a - 100mg - n/a]), (LAMOTRIGINE) (C - n/a - n/a - [n/a - 100mg - n/a]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - 50mg - n/a])	CER	
EU-EC-10000924972	15/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	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), Disorientation (n/a - Fatal - Results in Death)	COMBINATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CER	
EU-EC-10000934927	15/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 10d] - Intramuscular)	Not reported	CER	
EU-EC-1000093493	15/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	Abdominal pain upper (n/a - Fatal - Results in Death)	COMBINATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CER	
EU-EC-1000092609	15/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000092385	15/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000092024	14/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	SEENI (BENZFLAZOL) (S - n/a - n/a - [n/a - n/a - n/a]), BECLOMETHASONE PROPIONATE, FORMOTEROL, FLUTAMIDE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL, FLUTAMIDE HYDRATE, BECLOMETHASONE DIPROPIONATE PH. EUR., FORMOTEROL, FLUTAMIDE HYDRATE, BECLOMETHASONE DIPROPIONATE PH. EUR., FORMOTEROL, FLUTAMIDE HYDRATE, BECLOMETHASONE DIPROPIONATE ANHYDROUS (C - n/a - n/a -), (FENOTEROL, FENOTEROL BROMIDE, IPRATROPIUM BROMIDE, FENOTEROL, FENOTEROL BROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE) (C - n/a - n/a -), PINDOLOL, RISPERIDONE, THEOPHYLLINE ANHYDROUS (C - n/a - n/a -), (SALURITAMOL, SALURITAMOL, NICKERDOL, SALURITAMOL SULFATE) (C - n/a - n/a -)	Not reported	CER
EU-EC-1000090039	14/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000090039	14/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (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]), (DIOCALCOPROL, CALCIUM CARBONATE) (C - n/a - n/a - [n/a - n/a - n/a]), (BOMETASONE) (C - n/a - n/a - [n/a - n/a - n/a]), (NAPROXEN, NAPROXEN SODIUM, NAPROXEN ANHYDROUS) (C - n/a - n/a - [n/a - 500mg - n/a]), PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM BESILATE (C - n/a - n/a - [n/a - 40mg - n/a]), (TRAMADOL, TRAMADOL HYDROCHLORIDE) (C - n/a - n/a - [n/a - 100mg - n/a])	CER	
EU-EC-1000191174	14/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000192283	14/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	Not reported	CER	
EU-EC-1000098147	11/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Circulatory collapse (n/a - Unknown - Caused/Not Caused/Not Reported), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Impropriate schedule of product administration (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CER	
EU-EC-1000098236	11/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CER	
EU-EC-1000098479	10/06/2021	Spontaneous	Non-Healthcare Professional	Not available	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Metal impairment (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CER	
EU-EC-1000098643	10/06/2021	Spontaneous	Healthcare Professional	Not available	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/Not Caused/Not Reported), Pyrexia (n/a - Unknown - Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000098172	10/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000097089	10/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000097409	10/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000097417	10/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death), Pain: venous thrombosis (n/a - Not Recovered/Not Resolved -), Thrombosis (n/a - Not Recovered/Not Resolved -)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000097140	10/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000097431	10/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death), Thrombosis (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	Not reported	CER	
EU-EC-1000097247	10/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Adult	Male	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 10d] - Intramuscular)	LANTUS (INSULIN GLARGINE) (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]), (SODIUM VALPROATE, VALPROIC ACID) (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	CER
EU-EC-1000097257	10/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Female	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 10d] - Intramuscular)	Not reported	CER	
EU-EC-1000097254	10/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	CER	
EU-EC-1000097278	10/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a])	(ATORVASTATIN, ATORVASTATIN CALCIUM) (C - n/a - n/a -), (LAMOTRIGINE) (C - n/a - n/a -)	Not reported	CER
EU-EC-1000095192	09/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMBINATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CER	
EU-EC-1000095919	09/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMBINATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CER	
EU-EC-1000095106	09/06/2021	Spontaneous	Non-Healthcare Professional	Not available	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	Chest pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Hypotension (n/a - Not Recovered/Not Resolved -), Circulatory collapse (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown -)	COMBINATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a])	Not reported	CER	
EU-EC-1000095701	09/06/2021	Spontaneous	Healthcare Professional	Not available	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown -)	COMBINATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	CALCIUM, CALCIUM CARBONATE, CALCIUM CITRATE, CALCIUM ION (C - n/a - n/a -), (DIOCALCOPROL) (C -		

EU Lead Number	EV Gateway Review Date	Report Type	Primary Cause Qualification	Primary Source Country Regulatory Authority	Literature Reference	Patent Age Group	Patent Age Group (as per report)	Patent Sex	Patent Age Group	Reaction List PT (Duration 7 Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Admitted Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form	
EU-EC-100084192	06/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 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 - Anticoagulation - n/a - [n/a - n/a - n/a]); BENKORILUMETHIOLIDE, POTASSIUM CHLORIDE (C - Hypertension - n/a - [n/a - n/a - Oral]); METFORMIN HYDROCHLORIDE (C - Diabetes mellitus - n/a - [n/a - n/a - Oral]); SMAPREL (C - n/a - n/a - [n/a - n/a - Oral]); SIBURSTATIN (C - n/a - n/a - [n/a - n/a - Oral])	EUR	
EU-EC-100084194	06/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Fatal - Results in Death, Life Threatening), Agitation (n/a - Fatal - Results in Death, Life Threatening), Anxiety (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), Panic (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	EUR	
EU-EC-100084218	06/06/2021	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 -), Miasma (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(BENZONATE) (C - n/a - n/a - [n/a - 300mg - Oral]); NAPROXEN (C - n/a - n/a - [n/a - 1000mg - Oral])	EUR	
EU-EC-100084207	06/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084200	06/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084207	06/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084279	06/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Female	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 -), Purpura (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084273	06/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084200	06/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	EUR	
EU-EC-100084207	06/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d] - [n/a - Intramuscular])	ALPRAZOLAM (C - n/a - n/a -)	Not reported	EUR
EU-EC-100084207	06/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), 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), Hypotension (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])	PHENOCOCTONINE, PHENOCOCTONINE BROMIDE (C - Myasthenia gravis - n/a - [n/a - n/a - n/a])	EUR	
EU-EC-100084208	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084207	07/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084200	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyloric (n/a - Unknown -), Aphasia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyloric (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	EUR	
EU-EC-100084207	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Aphasia (n/a - Fatal - Results in Death), Pyloric (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084207	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - [DP] - Intramuscular])	Not reported	EUR
EU-EC-100084272	06/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac failure (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 - Intramuscular])	Not reported	EUR	
EU-EC-100084200	04/06/2021	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 - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	EUR	
EU-EC-100084215	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Female	Anxiety (n/a - Fatal - Results in Death), Blood glucose abnormal (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Constipation 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), Vision loss (n/a - Fatal - Results in Death), Visual impairment (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - n/a])	Not reported	EUR	
EU-EC-100084208	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])	(ACETYSALICYLIC ACID) (C - n/a - n/a -), ALPRAZOLAM (C - n/a - n/a -), ALCOLOONE, ALCOLOONE BESILATE (C - n/a - n/a -), GLYCEROL TRINITRATE (C - n/a - n/a -), NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE (C - n/a - n/a -), SIBURSTATIN (C - n/a - n/a -), SPIRONOLACTONE (C - n/a - n/a -), TRIMETAZIDINE DIHYDROCHLORIDE (C - n/a - n/a -)	EUR	
EU-EC-100084200	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084200	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 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])	Not reported	EUR	
EU-EC-100084200	04/06/2021	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	EUR	
EU-EC-100084200	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - 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 - n/a]); (METHYLPREDNISOLONE) (C - n/a - n/a - [n/a - n/a - n/a])	EUR	
EU-EC-100084200	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084200	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, 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]); ALLOPURINOL (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 - n/a - Subcutaneous]); FUROSEMIDE (C - n/a - n/a - [n/a - n/a - Oral]); GLYCEROL (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])	EUR	
EU-EC-100084200	03/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebral 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), Bites (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	EUR	
EU-EC-100084204	03/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain upper (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1d] - [DP] - Intramuscular)	Not reported	EUR	
EU-EC-100084200	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	EUR	
EU-EC-100084209	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084276	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 - Intramuscular])	Not reported	EUR	
EU-EC-100084270	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - 3mL - n/a])	PHENPROCOLONE (C - n/a - n/a -)	EUR	
EU-EC-100084223	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])	Not reported	EUR	
EU-EC-100084484	31/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	EUR	
EU-EC-100084709	31/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Female	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]); (BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]); (BILLYSINE ACETYSALICYLATE) (C - Cardiovascular accident - Not applicable - [n/a - n/a - n/a]); (NITAZEPAN) (C - n/a - n/a - [n/a - n/a - n/a]); (SPIRONOLACTONE) (C - n/a - n/a - [n/a - n/a - n/a])	EUR	
EU-EC-100084274	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	EUR	
EU-EC-100084212	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Both temperature increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Miasma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	XULTOPHY (SULFADIAZINE, NISULIN DELGIDEX) (C - n/a - n/a -), (AMOXICILIN, INDAPAMIDE, PERINDOPRIL ARGININE, INDAPAMIDE, ALCOLOONE BESILATE, PERINDOPRIL ARGININE) (C - n/a - n/a -), (BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - n/a - n/a -), (DIGOXIN) (C - n/a - n/a -), (DOMAZON, DOMAZON MESILATE) (C - n/a - n/a -), (METFORMIN HYDROCHLORIDE) (C - n/a - n/a -), (METHYLPREDNISOLONE DIHYDROGEN PHOSPHATE) (C - n/a - n/a -), (TROPICAMID, TROPICAMID BROMIDE, TROPICAMID BROMIDE MONOHYDRATE) (C - n/a - n/a -), (NIFEDIPINE SODIUM, WARFARIN SODIUM CLATHRATE) (C - n/a - n/a -)	EUR	
EU-EC-100084119	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084190	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Adult	No	Death (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death)	COVID-19 mRNA VACCINE (NUNCLEOSIDE MODIFIED) COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084276	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084200	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COVID-19 mRNA VACCINE (NUNCLEOSIDE MODIFIED) COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084200	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death), Deep vein thrombosis (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084200	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Miasma (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-1000841989	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d] - [DP] - Intramuscular)	Not reported	EUR	
EU-EC-100084200	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	COMPROVEL (HYDROCHLORAZIDE, IRRESARTAN) (C - n/a - n/a -), XARELTO 20 MG FILM COATED TABLETS (RIVAROXABAN) (C - n/a - n/a -), (AMODIAZOLE, AMODIAZOLE HYDROCHLORIDE) (C - n/a - n/a -), (NETROPIDOL FUMARATE) (C - n/a - n/a -)	EUR	
EU-EC-100084206	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Somnolence (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	EUR	
EU-EC-100084208	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Death (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition), Meconium aspiration syndrome (n/a - Unknown - Other Medically Important Condition), Placental abruption (n/a - Unknown - Other Medically Important Condition), Chorioamnionitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transperitoneal - Male in CSR])	(CRIGABOROLE) (C - Dermatitis atopic - n/a - [n/a - n/a - Transperitoneal]); (LORAZEPAM) (C - Hypersensitivity - n/a - [n/a - 10mg - n/a])	EUR	
EU-EC-100084215	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	06-85 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	EUR	
EU-EC-100084200	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Miasma (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	EUR	
EU-EC-100084183	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	EUR	
EU-EC-100084200	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	EUR	
EU-EC-100084200	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	06-85 Years	Not Specified	Male	No	Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), 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 - Male in CSR])	APXIBAN (RIVAROXABAN) (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 -), (EZETIMIBE) (C - n/a - n/a -), (FERROUS FUMARATE) (C - n/a - n/a -), (NICOTINOL) (C - n/a - n/a -), (PARACETAMOL) (C - n/a - n/a -), (PROLISANTIN, ROSIGLIXATIN CALCIUM) (C - n/a - n/a -)	EUR	

EU Local Number	EV Summary Reference Code	Report Type	Primary Country Qualification	Primary Country Regulatory Reference	Literature Reference	Patent Group	Patent (per report)	Patent (per report)	Patent (per report)	Patent (per report)	Reaction List (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)	CSR Form
EU-EC-100080357	27/05/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	No	Body temperature increased (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Death (01 - Fatal - Results in Death, CauseProlonged Hospitalisation), Decreased appetite (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Delirium (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Disorientation (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Phonemia (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[TRACOL, TAPLUPROST] (C - n/a - n/a -)	C18
EU-EC-100080408	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100080472	27/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100080503	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death, CauseProlonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100080519	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death, CauseProlonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100082812	26/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	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), Paresthesia (n/a - Fatal - Results in Death), Spores (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	TEMOZOLOMIDE ACCORD [TEMZOLOMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), ECTOPROSTINE OCTOYLOL ACETATE (C - n/a - n/a - [n/a - n/a - n/a]), AZULECT [RASAGILINE, RASAGILINE 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]), JANUVIA [SATAGLITIN, SATAGLITIN PHOSPHATE, SATAGLITIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), TRESIBA [INSULIN DEGLIUCER] (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])	C18
EU-EC-100082837	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (01 - Fatal - Results in Death, CauseProlonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100082917	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100083003	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Acquired haemophilia (n/a - Fatal - Results in Death), Anti factor VIII antibody positive (n/a - Fatal - Results in Death), Anti fibrinogen (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Melaena (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - intramuscular])	[ALLOPURINOL] (C - Gout - n/a - n/a - Oral), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiac failure - n/a - n/a - Oral), [FLUORENOL] (C - Cardiac failure - n/a - n/a - Oral), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ZINC] (C - n/a - n/a - [n/a - n/a - Oral])	C18
EU-EC-100083068	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Cardiac 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), Histiocytic (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, CODEINE PHOSPHATE HEMHYDRATE] (C - Pain - Unknown - [n/a - n/a - n/a])	C18
EU-EC-100083069	26/05/2021	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 - Not applicable - [n/a - 20F - intramuscular])	Not reported	C18
EU-EC-100083082	26/05/2021	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) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100083090	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation, Other Medically Important Condition), Dysnoea recurrence (n/a - Unknown -), Dysnoea (n/a - Unknown - CauseProlonged Hospitalisation), Lip swelling (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pharyngeal swelling (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Pyrexia (n/a - Unknown -), Seizure (n/a - Unknown - CauseProlonged Hospitalisation, 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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 120mg - n/a]), [FAMOTIDINE] (C - n/a - n/a - [n/a - 20mg - n/a]), [FLUCICAZONE FURATE, VILANTEROL TRIFENATE, FLUCICAZONE, VILANTEROL] (C - Asthma - n/a - [n/a - n/a - n/a]), [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 D] (C - n/a - n/a - [n/a - 1000IU - n/a])	C18
EU-EC-100083154	26/05/2021	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	C18
EU-EC-100083169	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	No	Cardiac failure acute (01 - Fatal - Results in Death), Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083193	26/05/2021	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 - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083199	26/05/2021	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 - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083180	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100083240	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - intramuscular])	[ACEVOLOMAROL] (C - n/a - n/a -), [GLUCOCORT] (C - n/a - n/a - [n/a - 80mg - n/a]), [INDAPAMIDE, PIREMOLOL] (C - n/a - n/a -), [INDAPAMIDE] (C - n/a - n/a - [n/a - 1.5mg - n/a]), [MELNORCAM] (C - n/a - n/a - [n/a - 15mg - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 500mg - n/a]), [PIANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [SUETAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 25mg - n/a])	C18
EU-EC-100083280	26/05/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death, Life Threatening, CauseProlonged Hospitalisation), 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	C18
EU-EC-100083300	26/05/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	Not Specified	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	C18
EU-EC-100083309	26/05/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	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	C18
EU-EC-100083356	26/05/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death), Melaena (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083366	26/05/2021	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 - Drug withdrawn - [n/a - 10F - intramuscular])	Not reported	C18
EU-EC-100083389	26/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	19-64 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown - CauseProlonged Hospitalisation), Fatigue (n/a - Unknown - CauseProlonged Hospitalisation), Seizure (n/a - Unknown - CauseProlonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083408	26/05/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	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	C18
EU-EC-100083419	26/05/2021	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 [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083514	26/05/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	19-64 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	C18
EU-EC-100083570	26/05/2021	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 [TOZINAMERAN] (S - immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083798	26/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	C18
EU-EC-100083813	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death, CauseProlonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 5mL - intramuscular])	[BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - Drug withdrawn -), [GLYCERYL TRINTRAITE] (C - n/a - n/a - [n/a - Transdermal]), [PVIDONE K25, THEOPHYLLINE, THEOPHYLLINE ANHYDRUS] (C - n/a - n/a -), [SPRONOLACTONE] (C - n/a - n/a - [n/a - n/a - Oral])	C18
EU-EC-100083282	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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	C18
EU-EC-100083386	26/05/2021	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 - Not applicable - [n/a - 10F - intramuscular])	Not reported	C18
EU-EC-100083336	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 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 reported	C18
EU-EC-100083207	26/05/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	No	Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Oropharyngeal pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Embolism (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE (HYDRATE)] (C - Asthma - n/a - [n/a - n/a - n/a]), [ESTRADIOL] (C - Hormone replacement therapy - n/a - [n/a - n/a - n/a]), [FLUCICAZONE, FLUCICAZONE HYDROCHLORIDE] (C - Depressed mood - n/a - [n/a - n/a - n/a]), [LEVONORGESTREL, LEVONORGESTREL MICRONISED] (C - n/a - n/a - [n/a - n/a - n/a]), [SMFIRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a])	C18
EU-EC-100081467	26/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	19-64 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death), Oropharyngeal pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Embolism (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE (HYDRATE)] (C - Asthma - n/a - [n/a - n/a - n/a]), [ESTRADIOL] (C - Hormone replacement therapy - n/a - [n/a - n/a - n/a]), [FLUCICAZONE, FLUCICAZONE HYDROCHLORIDE] (C - Depressed mood - n/a - [n/a - n/a - n/a]), [LEVONORGESTREL, LEVONORGESTREL MICRONISED] (C - n/a - n/a - [n/a - n/a - n/a]), [SMFIRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a])	C18
EU-EC-100081932	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100081965	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death, CauseProlonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100081796	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100082255	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - immunisation - n/a - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100086917	18/05/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death, 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	C18
EU-EC-100083001	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death, Life Threatening, CauseProlonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (01 - Fatal - Results in Death, Life Threatening, CauseProlonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - intramuscular])	[EXLON [BIVASTINUM] (C - Vascular dementia - n/a - [n/a - 10F - Oral]), [ACELSALICILIC ACID] (C - Anticoagulant therapy - n/a - [n/a - 10F - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 10F - Oral]), [GLYCERYL TRINTRAITE] (C - n/a - n/a - [n/a - 10F - Cutaneous]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 50mg - Oral])	C18
EU-EC-100083006	19/05/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Convulsion 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 - [n/a - n/a - n/a])	Not reported	C18
EU-EC-100083014	19/05/2021	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), Dysnoea (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]), [TOLEDO SOLUSTAR [INSULIN GLARGINE]] (C - n/a - n/a - [n/a - 1.6mL - Subcutaneous]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - 10mg - Oral]), [DOXICALFEROL] (C - n/a - n/a - [n/a - n/a - Oral]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - Oral]), [LISINAPRIL, LISINAPRIL DEHYDRATE] (C - n/a - n/a - [n/a - 2.5mg - Oral]), [SALBUTAMOL, SALBUTAMOL] (C - n/a - n/a - [n/a - 360mg - Oral])	C18
EU-EC-100083021	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100083079	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death, CauseProlonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100083064	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (01 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - intramuscular])	Not reported	C18
EU-EC-100086006	18/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[KISUN [KISUN] [KISUN], HELIUM HELIUM BROMIDE, KISUN HELIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [JANUVIA [SATAGLITIN, SATAGLITIN PHOSPHATE, SATAGLITIN PHOSPHATE MONOHYDRATE]] (C - n/a - n/a - [n/a - 50mg - n/a]), [ACELSALICILIC ACID] (C - n/a - 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 TRINTRAITE, GLYCERYL TRINTRAITE SOLUTION] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE B] (C - n/a - n/a - [n/a - 500mg - n/a]), [VALSARTAN, VALSARTAN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10F - n/a])	C18
EU-EC-100086101	18/05/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - Results in Death, CauseProlonged Hospitalisation), Lymphoedema (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - CauseProlonged Hospitalisation), Peripheral swelling (n/a - Unknown			

EU Lead Number	EU Gateway Review Date	Report Type	Primary Country	Primary Disease	Literature Reference	Patent Reg. Status	Patent (as per report)	Patent No.	Patent Title	Reaction List PT (Duration / Outcome - Seriousness Criteria)	Suspect/Involved Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/ Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CCR Form
EU-EC-100064154	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Hypertension (15 - Fatal - Results in Death), Nausea (14 - Fatal - Results in Death), Sopor (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	[LORAZEPAM] (C - n/a - n/a - [14 - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [14 - n/a - n/a]), [TRAZODONE TRIAZOLONE HYDROCHLORIDE] (C - n/a - n/a - [14 - n/a - n/a]), [LANTUS (INSULIN GLARGINE)] (C - Type 2 diabetes mellitus - n/a - [14 - n/a - n/a]), [NOVORAPD (INSULIN ASPART)] (C - Type 2 diabetes mellitus - n/a - [14 - n/a - n/a]), [XARELTO (RIVAROXABAN)] (C - Atrial fibrillation - n/a - [15mg - Oral]), [BISOPROLOL FLUMARATE] (C - Hypertensive heart disease - n/a - [14 - n/a - n/a]), [RUCLOSAR (RUCIPATEROL FLUMARATE DIPHOSPHATE, FORMOTEROL FLUMARATE, BUDESONIDE)] (C - Chronic obstructive pulmonary disease - n/a - [14 - n/a - n/a]), [DOPHANE] (C - n/a - n/a - [14 - n/a - n/a]), [FURSEMID] (C - n/a - n/a - [14 - n/a - n/a]), [FURSEMID] (C - n/a - n/a - [14 - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [14 - n/a - n/a]), [METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [14 - n/a - n/a]), [NYSSTATIN NYSSTATIN ZINC OXIDE] (C - Oral candidiasis - n/a - [14 - n/a - n/a]), [DOXEN] (C - n/a - n/a - [14 - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [14 - n/a - n/a]), [POLYGLUCINE] (C - n/a - n/a - [14 - n/a - n/a]), [ROSLIVASTATIN ROSLIVASTATIN CALCIUM] (C - Dyslipidemia - n/a - [14 - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (C - Insomnia - n/a - [14 - n/a - n/a])	C18
EU-EC-100064178	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [14 - 100] - Intramuscular)	NOT AVAILABLE (C - n/a - Dose not changed - [14 - 10mg - n/a]), NOT AVAILABLE (C - n/a - Dose not changed - [14 - 5mg - n/a]), NOT AVAILABLE (C - n/a - Dose not changed - [14 - 5mg - n/a]), TRALENTA 5 MG FILM-COATED TABLETS [TRALENTA] (C - n/a - Dose not changed - [14 - 5mg - n/a]), TRITICO RETI BL 150MG [NOT AVAILABLE] (C - n/a - Dose not changed - [14 - 150mg - n/a]), [ACETYSALICYLIC ACID] (C - n/a - Dose not changed - [14 - 100mg - n/a]), [AMODIPINE BESILATE] (C - n/a - Dose not changed - [14 - 5mg - n/a]), [DOLICACIPROLOL] (C - n/a - Dose not changed - [14 - 350mg - n/a]), [METAZOLOL SODIUM MONOHYDRATE] (C - Plan - Dose not changed - [14 - 250mg - n/a]), [NIFEDIPINE] (C - Antihypertensive - Dose not changed - [14 - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [14 - n/a - n/a]), [SPERIDONE] (C - n/a - n/a - [14 - n/a - n/a])	C18
EU-EC-100064205	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death), General physical health deterioration (14 - Fatal - Results in Death), Pyrexia (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [14 - n/a - Intramuscular])	NOT REPORTED	C18
EU-EC-100064303	14/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Life Threatening), Dermatitis (14 - Not Recovered/Not Resolved - Life Threatening)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100064325	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-100064479	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (201 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (101 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (14 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (14 - Unknown - Caused/Prolonged Hospitalisation), Somnolence (14 - Unknown -)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100064581	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death), Fatigue (14 - Not Recovered/Not Resolved -), Hypotension (14 - Not Recovered/Not Resolved -), Nausea (14 - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100064642	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100064634	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death), Fatigue (14 - Not Recovered/Not Resolved -), Headache (14 - Not Recovered/Not Resolved -), Hypotension (14 - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100064697	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - Intravenous (not otherwise specified)])	NOT REPORTED	C18
EU-EC-100064920	14/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Asthenia (14 - Not Recovered/Not Resolved -), Chills (14 - Not Recovered/Not Resolved -), Death (14 - Fatal - Results in Death), Fatigue (14 - Not Recovered/Not Resolved -), Hot flush (14 - Not Recovered/Not Resolved -), Lymphoedema (14 - Not Recovered/Not Resolved -), Pyrexia (14 - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066014	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-100066055	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	[ALLOPURINOL] (C - n/a - n/a - [14 - 100mg - Oral]), [BISOPROLOL FLUMARATE, BISOPROLOL FLUMARATE, ACETYSALICYLIC ACID, BISOPROLOL, HEMIFUMARATE] (C - n/a - n/a - [14 - 5mg - Oral]), [DOLICACIPROLOL] (C - n/a - n/a - [14 - 1000u - n/a]), [DOMAZON, DOMAZON MESILATE] (C - n/a - n/a - [14 - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [14 - 50mg - Oral]), [NIFEDIPINE] (C - n/a - n/a - [14 - n/a - n/a])	C18
EU-EC-100066482	14/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (14 - Unknown - Caused/Prolonged Hospitalisation), Chills (14 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Hypogonadism (14 - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (14 - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066589	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (14 - Fatal - Results in Death), Nausea (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	[AMODIPINE, AMODIPINE] (C - Hypertension - n/a - [14 - 10] - Oral), [NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE] (C - Hypertension - n/a - [14 - 2.5mg - Oral])	C18
EU-EC-100066533	14/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	COVID-19 (14 - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - Intramuscular])	[PREDNISOLONE] (C - COVID-19 - n/a - [14 - 40mg - n/a])	C18
EU-EC-100066271	13/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 100] - n/a)	NOT REPORTED	C18
EU-EC-100066314	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-100066318	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Elderly	Male	No	COVID-19 (14 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066305	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Drug ineffective (14 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Hypertensive heart disease (14 - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066300	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - n/a])	NOT REPORTED	C18
EU-EC-100066308	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066303	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-100066177	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066392	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-100066043	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Patient count decreased (14 - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066042	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Dysthymia (14 - Fatal - Results in Death), Loss of consciousness (14 - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	[CHOLBIPHENYLATE, SMVASTATIN] (C - n/a - n/a - [14 - n/a - Oral]), [BAMIDIPINE DIIHYDROCHLORIDE] (C - n/a - n/a - [14 - n/a - Oral]), [VALSARTAN] (C - n/a - n/a - [14 - n/a - n/a])	C18
EU-EC-100066085	11/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	COVID-19 (14 - Fatal - Results in Death), Drug ineffective (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066791	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Hypertension (14 - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	[SERENIDA REPENS] (C - Postural disorder - n/a - [14 - n/a - n/a])	C18
EU-EC-100066921	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), COVID-19 (14 - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), General physical health deterioration (14 - Unknown - Caused/Prolonged Hospitalisation), Hypothroidism (14 - Unknown -), Oxygen saturation decreased (14 - Recovered/Resolved - Caused/Prolonged Hospitalisation), PCC2 abnormal (14 - Recovered/Resolved - Caused/Prolonged Hospitalisation), Renal failure (14 - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sudden hearing loss (14 - Unknown - Other Medically Important Condition), Tremor (14 - Unknown -)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066949	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066912	11/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Malaise (14 - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066117	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Male	No	Asthenia (14 - Not Recovered/Not Resolved -), Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 100] - Intramuscular)	NOT REPORTED	C18
EU-EC-100066156	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death), Fatigue (14 - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-1000661629	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (14 - Not Recovered/Not Resolved -), Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-1000661632	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-1000661638	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Elderly	Female	No	Cardiac dissection (14 - Unknown -), Cough (14 - Unknown -), Death (14 - Fatal - Results in Death), Dyspnoea (14 - Unknown -), Diarrhoea (14 - Unknown -), Performance status depressed (14 - Unknown -), Somnolence (14 - Unknown -)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-1000661639	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-1000661465	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-100066314	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Asthenia (14 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (14 - Unknown - Other Medically Important Condition), Fatigue (14 - Unknown - Other Medically Important Condition), Gas instability (14 - Unknown - Other Medically Important Condition), Hypertension (14 - Unknown - Other Medically Important Condition), Ischaemic stroke (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Death (14 - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [14 - 5mg - n/a])	C18	
EU-EC-1000661996	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-1000661929	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-1000662618	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 95 Years	Not Specified	Female	No	Cardio-respiratory arrest (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Tumour thrombosis (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	[ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Unknown - [14 - n/a - n/a]), [BETALDOL HYDROCHLORIDE] (C - n/a - Unknown - [14 - n/a - n/a]), [MESALAZINE] (C - n/a - Unknown - [14 - n/a - n/a]), [PIANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [14 - n/a - n/a]), [PILSACICUMIDE BION COMPLEX] (C - n/a - Unknown - [14 - n/a - n/a])	C18
EU-EC-100066952	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest dissection (14 - Recovered/Resolved -), Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066942	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (14 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-100066969	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [14 - 100] - Intramuscular), [CYMBAZEMINE] (S - n/a - n/a - [14 - 10mg - n/a]), [DOMPERIDONE] (S - n/a - n/a - [14 - 30mg - n/a]), [ESCITALOPRAM] (S - n/a - n/a - [14 - 10mg - n/a])	C18	
EU-EC-1000669870	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [14 - 100] - Intramuscular)	NOT REPORTED	C18
EU-EC-100066987	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [14 - 3mL - Intramuscular])	NOT REPORTED	C18
EU-EC-1000669707	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [14 - n/a - n/a])	NOT REPORTED	C18
EU-EC-1000669723	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (14 - Fatal - Results in Death), General physical health deterioration (14 - Fatal - Results in Death), Urterospone to stimu (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [14 - n/a - n/a])	[ELIGUS (APRAXAN)] (C - n/a - n/a - [14 - n/a - n/a]), [ZYREXA (ELANZAPINE)] (C - n/a - n/a - [14 - n/a - n/a]), [CARBOMER, CARBOMER 98] (C - n/a - n/a - [14 - n/a - n/a]), [LEVOTHYROXINE] (C - n/a - n/a - [14 - n/a - n/a]), [MIFEDIPINE] (C - n/a -	

EU Local Number	EV Primary Review Date	Report Type	Primary Cause Qualification	Primary Source Country (Regulatory Purpose)	Literature Reference	Patent Age Group	Patent Sex	Patent Race	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])	CSR Form	
EU-EC-10007491	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Adult	Male	Death (n=1 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	[TAMSOLOLIN, TAMSOLOLIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a]), [NINAVIR, NINAVIRAN SODIUM] (C - n/a - n/a - [n/a - 2.5mg - n/a - More in CSR])	CSR	
EU-EC-100083028	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Female	Acute kidney injury (n/a - Unknown - Caused/Not Caused/Not Reported), Acute respiratory distress syndrome (n/a - Unknown - Caused/Not Caused/Not Reported), Acute sinusitis (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=1 - Fatal - Results in Death), Dehydration (n/a - Unknown - Caused/Not Caused/Not Reported), Diarrhoea (n/a - Unknown -), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovered/Not Recovered -), Genitourinary infection (n/a - Unknown - Caused/Not Caused/Not Reported), Hypotension (n/a - Unknown - Caused/Not Caused/Not Reported), Inappropriate schedule of product administration (n/a - Unknown -), Mabixia (n/a - Recovered/Not Recovered -), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Not Caused/Not Reported), Myalgia (n/a - Unknown -), Nausea (n/a - Unknown -), Ofit labet (n/a - Unknown -), Pulmonary oedema (n/a - Unknown - Caused/Not Caused/Not Reported), Pyrexia (n/a - Unknown -), Shock (n/a - Unknown - Caused/Not Caused/Not Reported, 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/Not Caused/Not Reported)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular] - More in CSR)	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - n/a]), [HYDROCODONE] (C - Hypertension - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-100083506	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Asthma (n/a - Not Recovered/Not Recovered -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Recovered -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	[ACETYL SALICYLIC ACID] (C - n/a - Dose not changed - [n/a - 100mg - n/a]), [OLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 1DF] - n/a), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [METABOLITE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 300mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE, METOPROLOL TARTRATE PH. EUR.] (C - n/a - Dose not changed - [n/a - 47.5mg - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 1DF] - n/a)	CSR	
EU-EC-100083030	15/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-84 Years	Not Specified	Male	Abdominal distension (n/a - Unknown -), Cardiomyopathy (n/a - Unknown -), Condition aggravated (n/a - Unknown -), Coryza (n/a - Unknown -), Cough (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])	[BETNOL, RETINOL, PALMITATE, DEHPANTHENOL] (C - n/a - Dose not changed - [n/a - 350mg] - n/a)	CSR	
EU-EC-100083031	15/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-84 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 - [1d - n/a - n/a])	[ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIAZODIN, DIAZODIN MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FRANCIPTIN, FRANTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [NICOTINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSOLOLIN, TAMSOLOLIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - n/a]), [ZIPROLOL] (C - n/a - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-100083032	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	CSR	
EU-EC-100083033	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (D - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU-EC-100083034	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Mabixia (n/a - Unknown -), Seizure (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-100083035	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Abdominal pain upper (n/a - Not Recovered/Not Recovered -), Asthma (n/a - Not Recovered/Not Recovered -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 1DF] - Intramuscular)	[ACETYL SALICYLIC ACID, D,L-LYSINE ACETYL SALICYLATE, LYSINE ASPRIN, LYSINE ACETYL SALICYLIC ACID] (C - n/a - n/a -), [BISOPROLOL FUMARATE] (C - n/a - n/a -), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - n/a -), [MAGNESIUM, 300, POTASSIUM OXALATE, SODIUM CARBONATE, SODIUM CHLORIDE, SODIUM CHLORIDE ANHYDROUS, MACROGOL 300, SODIUM HYDROGEN CARBONATE, POTASSIUM CALCIUM CALCIUM, SODIUM CHLORIDE, SODIUM SULFATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE, ANHYDROUS], [MICROGOL 300] (C - n/a - n/a -), [MILNEDICINE, MILNEDICINE DIHYDROGEN PHOSPHATE] (C - n/a - n/a -), [ZINC OLEATE] (C - n/a - n/a -)	CSR	
EU-EC-100083036	15/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	16-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR	
EU-EC-100083037	15/04/2021	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 - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083038	15/04/2021	Spontaneous	Healthcare Professional	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), Hypertension (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])	[ACETYL SALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hypertension - n/a - [n/a - 20mg - Oral]), [DIAZEPAM, DIAZEPAM DIHYDRATE] (C - Demerol - n/a - [n/a - 5mg - Oral]), [ESICLORFENIRAM DIALLATE] (C - Depression - n/a - [n/a - 5mg - Oral]), [SABAPENTIN] (C - Pain - n/a - [n/a - 300mg - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [NAPROXEN SODIUM] (C - Pain - n/a - [n/a - 220mg - Oral]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Sleep temperature increased - Pain - n/a - [n/a - 200mg - Oral]), [DIETHANNE, DIETHANNE FUMARATE] (C - Alcohol withdrawal, Demerol - n/a - [n/a - 250mg - Oral]), [FRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Pain - n/a - [n/a - 100mg - n/a])	CSR	
EU-EC-100083039	15/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	16-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083040	15/04/2021	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 -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	CSR	
EU-EC-100083041	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083042	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Elderly	Male	Cardiovascular accident (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Caused/Not Reported), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Caused/Not Reported), Disturbance in attention (n/a - Not Recovered/Not Recovered -), Hypertension (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Caused/Not Reported), Ischaemic stroke (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Caused/Not Reported)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083043	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Female	Death (D - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	[ACETYL SALICYLIC ACID] (C - n/a - n/a -), [ALLOPURINOL] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE, PERINDOPRIL ARGININE, INDAPAMIDE, AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - n/a - n/a -), [FENOFIBRATE] (C - n/a - n/a -), [PRAZOSIN] (C - n/a - n/a -), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a -), [URAPIDIL, URAPIDIL HYDROCHLORIDE] (C - n/a - n/a -)	CSR	
EU-EC-100083044	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083045	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083046	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083047	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 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-100083048	15/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported), Dyspnoea (2d - Fatal - Results in Death, Caused/Not Caused/Not Reported)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083049	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Female	Death (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 - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [BORFINER, SULFATE] (C - Dyspepsia - 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])	CSR	
EU-EC-100083050	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083051	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Phonophobia (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083052	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Female	Asthma (n/a - Unknown -), Asthma (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Depression (n/a - Unknown -), General physical health deterioration (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR	
EU-EC-100083053	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Caused/Not Caused/Not Reported, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Caused/Not Caused/Not Reported, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-100083054	15/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Abdominal pain (n/a - Not Recovered/Not Recovered -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Not Recovered/Not Recovered -), Dyspnoea (n/a - Not Recovered/Not Recovered -), Fatigue (n/a - Not Recovered/Not Recovered -), Renal laboratory failure (n/a - Not Recovered/Not Recovered -), Shortness of breath (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR	
EU-EC-100083055	15/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-84 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Not Caused/Not Reported), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Not Recovered/Not Recovered -), Dyspnoea (n/a - Recovered/Not Recovered - Caused/Not Caused/Not Reported), Fatigue (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported), Headache (n/a - Recovered/Not Recovered - Caused/Not Caused/Not Reported), Hives (n/a - Unknown - Caused/Not Caused/Not Reported), Hypotension (n/a - Not Recovered/Not Recovered -), Muscular weakness (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported), Pneumonia (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported), Pulmonary embolism (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported), Pulmonary oedema (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported), Pulse abnormal (n/a - Not Recovered/Not Recovered - Caused/Not Caused/Not Reported), Therapeutic product effect incomplete (n/a - Not Recovered/Not Recovered -), Vaccination complication (n/a - Unknown - Caused/Not Caused/Not Reported)	FRIDAPSE (AMFAPRIPNONE) (S - Muscular weakness - Dose not changed - [n/a - 10mg - Oral - More in CSR]), FRIDAPSE (AMFAPRIPNONE) (S - Muscular weakness - Unknown - [n/a - 30mg - Oral - More in CSR]), 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 - Unknown])	CSR	
EU-EC-100083056	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Not Specified	Female	Death (D - 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 HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1DF] - n/a), [ANHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - 1DF] - n/a), [BUMETANIDE] (C - n/a - Unknown - [n/a - 1DF] - n/a), [FOSFOSODIUM, FOSFOSODIUM TRISODIUM] (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 - 1DF] - n/a), [PASSIFLORA INCARNATA DRY EXTRACT] (C - n/a - Unknown - [n/a - 1DF] - n/a), [PM2002] (C - n/a - Unknown - [n/a - 2DF] - n/a)	Not reported	CSR
EU-EC-100083057	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	CSR	

EU Lead Number	EV Gateway Review Date	Report Type	Primary Country	Primary Regulatory Authority	Literature Reference	Patent Group	Patent Type	Patent Status	Patent No.	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)	CSR Form	
EU/EC/100827465	12/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	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 (1d - Recovered/Resolved -), Mebaze (n/a - Not Recovered/Not Resolved -) Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	CSR	
EU/EC/100827604	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	BUPRENORPHINE (C - n/a - n/a -)	CSR	
EU/EC/100827654	12/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acromioclavicular joint (n/a - Unknown - Life Threatening), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown - Life Threatening), Urteropneumonia (n/a - Unknown - Life Threatening, Other Medically Important Condition)	TOZANMERAN (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BISOPROLOL, FLUMAZEMOL, BISOPROLOL, HEMIFLUMAZEMOL (C - Hypertension - n/a - [n/a - 125mg - Oral - More in CSR]), [BUPRENORPHINE] (C - Back pain - n/a - [n/a - n/a - Transdermal]), [CALCIUM GLUCONATE] (C - n/a - n/a -), FUROSEMIDE, FUROSEMIDE SODIUM (C - Hypertension - n/a [800d - n/a - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - 1g - Oral]), [QUETIAPINE] (C - n/a - n/a - [n/a - Oral]), [SODIUM PHOSPHATE] (C - n/a - n/a -) FENTANYL, FENTANYL, FENTANYL, CITRATES (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])	CSR	
EU/EC/100827811	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR	
EU/EC/100827827	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100827938	12/04/2021	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 - 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 -)	TOZANMERAN (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100828293	12/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	Not reported	CSR	
EU/EC/100828298	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Injection site (n/a - Product administration (n/a - Unknown -))	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	Not reported	CSR	
EU/EC/100828311	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	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 - Results in Death), Generalized tonic-clonic seizure (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU/EC/100828343	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Generalized tonic-clonic seizure (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Drug withdrawal - [1d - 1DF] - Intramuscular)	Not reported	CSR	
EU/EC/100828495	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	KIPPRA (ELEVETACETAM) (C - n/a - n/a -)	CSR	
EU/EC/100828503	08/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR	
EU/EC/100829033	09/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR	
EU/EC/100829096	09/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-84 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening), Drug withdrawal (n/a - Unknown - Life Threatening, Other Medically Important Condition), Mebaze (n/a - Recovered/Resolved - Life Threatening)	TOZANMERAN (TOZANMERAN) (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] (n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROCHLORIDE, CITALOPRAM HYDROCHLORIDE] (C - Depressed mood - n/a - [n/a - n/a - n/a])	CSR	
EU/EC/100829418	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZANMERAN (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	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, Supplemental therapy - n/a - [n/a - 1000mg - Oral]), [CITALOPRAM, HYDROCHLORIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - 10mg - Oral]), [DIOXINE] (C - Cardiac failure - n/a - [n/a - 25mg - Oral]), [DOMPERIDONE, HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [DORAZEPAM] (C - Anxiety, Insomnia - n/a - [10mg - 3mg - n/a]), [NEFINANTINE, HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [BISOPROLOL, SALFATE] (C - Dyspnoea, Pain - n/a - [120mg - 20mg - Oral]), [PARACETAMOL] (C - Analgesia - n/a - [500mg - n/a]), [PARACETAMOL] (C - Analgesia - n/a - [500mg - Oral])	Not reported	CSR
EU/EC/100829793	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZANMERAN (TOZANMERAN) (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, Supplemental therapy - n/a - [n/a - 1000mg - Oral]), [CITALOPRAM, HYDROCHLORIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - 10mg - Oral]), [DIOXINE] (C - Cardiac failure - n/a - [n/a - 25mg - Oral]), [DOMPERIDONE, HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [DORAZEPAM] (C - Anxiety, Insomnia - n/a - [10mg - 3mg - n/a]), [NEFINANTINE, HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [BISOPROLOL, SALFATE] (C - Dyspnoea, Pain - n/a - [120mg - 20mg - Oral]), [PARACETAMOL] (C - Analgesia - n/a - [500mg - n/a]), [PARACETAMOL] (C - Analgesia - n/a - [500mg - Oral])	Not reported	CSR
EU/EC/100829829	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829840	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829845	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829849	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829850	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829851	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829854	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829863	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100829894	09/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR	
EU/EC/100829897	09/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	CSR	
EU/EC/100829933	09/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Fgll (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Kidney infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin necrosis (n/a - Unknown -)	TOZANMERAN (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR	
EU/EC/100829939	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY (TOZANMERAN) (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR	
EU/EC/100829990	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - 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]), [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] (C - n/a - n/a - [n/a - n/a - n/a]), [SPRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1DF] - n/a), [DOLECALFEROL] (C - n/a - n/a - [n/a - 1DF] - n/a), [FLUTICASON, PROPIONATE, SALMETEROL] (C - n/a - n/a - [n/a - 1DF] - n/a), [PRAZOPROLOL, PRAZOPROLOL] (C - n/a - n/a - [n/a - 10DF] - n/a), [FAMBUSOLON, HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), FANTOPRIZOLE 30 MG - GASTRO-RESISTANT TABLET (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU/EC/100829992	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BAMIPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [KELON, PALPERIDONE PALMATE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR	
EU/EC/100829993	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [NOVORAPD 100 EM, OPLOSSING VOOR INJECTIE IN FLACON, [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a])	CSR	
EU/EC/100829994	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	CSR	
EU/EC/100829995	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	CSR	
EU/EC/100829996	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	PROXON (BISBUTANOL TERTRATE, BISBUTANOL TERTRATE MESILATE) (C - Cardiovascular accident prophylaxis - n/a - [n/a - 110mg - Oral]), [BIACOR, BIACOR] (C - Diabetes therapy - n/a - [n/a - 1mg - Oral]), [CYANOCOBALAMIN, HYDROXYCOBALAMIN] (C - Vitamin supplementation - n/a - [n/a - 1mg - Oral]), [FERROUS CHLORIDE TETRABOXYLATE, FERROUS ION] (C - n/a - n/a - [n/a - 8mg - 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 - 10DF] - Oral), [QUETIAPINE] (C - First-episode dementia - n/a - [n/a - 50mg - Oral]), [SALBUTAMOL, SALBUTAMOL, SULFATE] (C - Dyspnoea - n/a - [n/a - n/a - Respiratory Inhalation]), [XARIS TO (PRANDIGLIDARIN)] (C - n/a - n/a -), [BUKOSONIDE, BUKOSONIDE, MACROGOL 3350] (C - n/a - n/a -), [DOMPERIDONE, HYDROCHLORIDE] (C - n/a - n/a -), [DIPYRIDOL, FERROUS SALFATE, FERROUS SALFATE] (C - n/a - n/a -), [FUROSEMIDE] (C - n/a - n/a -), [HYDROXYCOBALAMIN] (C - n/a - n/a -), [LEVOTHYRONE, LEVOTHYRONE SODIUM] (C - n/a - n/a -), [MIRAZEPAM] (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 HYDROCHLORIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1047d - 40mg - n/a]), [LEVOTHYRONE, LEVOTHYRONE SODIUM] (C - n/a - n/a - [n/a - 25mg - n/a]), [SALBUTAMOL, SALBUTAMOL, SULFATE] (C - n/a - n/a - [n/a - 250mg - n/a - n/a])	Not reported	CSR
EU/EC/100829999	09/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiovascular 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), Thyroid infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Viral meningitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	TOZANMERAN (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU/EC/100830006	09/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	TOZANMERAN (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR	
EU/EC/100830007	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Blood creatinine 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)	COMIRNATY (TOZANMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	BRILOQUE (TICAGRELOR) (C - n/a - n/a - [n/a - 90mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 80mg - 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])	CSR	
EU/EC/100830008	09/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZANMERAN (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ATORVASTATIN (C - Hypercholesterolaemia - n/a - [n/a - n/a - n/a]), [DOLECALFEROL, CALCIUM CARBONATE] (C - Osteopenia - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [RAMPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a])	CSR	
EU/EC/100830009	09/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - Life Threatening), Communication disorder (n/a - Unknown - Life Threatening), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown - Life Threatening), Inappropriate schedule of product administration (n/a - Unknown -), Mebaze (n/a - Unknown - Life Threatening), Off label use (n/a - Unknown -)	TOZANMERAN (TOZANMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[VANCOMYCIN, VANCOMYCIN HYDROCHLORIDE] (C - Creative protein increased - n/a - [43d - n/a - n/a])	CSR	
EU/EC/100830010	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	ROSOVASTATIN, ROSOVASTATIN CALCIUM (C - Dyslipidaemia - n/a - [n/a - 1DF] - Oral)	CSR	
EU/EC/100830011	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZANMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	CSR	
EU/EC/100830012	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)				

EU Lead Number	EV Summary Report Date	Report Type	Primary Country of Origin (Regulatory Purpose)	Literature Reference	Patent (Age Group)	Patent (Sex)	Patent (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)	CSR Form		
										<p>(ACETYLCYSTEINE) (C - na - na - [na - 200mg - na]),</p> <p>(DICALCOPHEROL, CALCIUM, COLCALCOPHEROL, CALCIUM CARBONATE) (C - na - na - [na - 10PF - na]),</p> <p>(DICALCOPHEROL) (C - na - na - [na - 8000] - na),</p> <p>(EVANCOBALAMINE) (C - na - na - [na - 1mg - na]),</p> <p>(FERROUS SULFATE) (C - na - na - [na - 100mg - na]),</p> <p>(FOLIC ACID) (C - na - na - [na - 1mg - na]),</p> <p>(METOPROLOL, METOPROLOL TARTRATE) (C - na - na - [na - 25mg - na]),</p> <p>(NOCOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE) (C - na - na - [na - 10PF - na]),</p> <p>(OMEPRAZOLE) (C - na - na - [na - 20mg - na]),</p> <p>(VINCOSOLINE HYDROCHLORIDE) (C - na - na - [na - 5mg - na]),</p> <p>(PARACETAMOL) (C - na - na - [na - 1g - na]),</p> <p>(PREDNISOLONE) (C - na - na - [na - 10mg - na]),</p> <p>(DOPLOLOL) (C - na - na - [na - 5mg - na]),</p> <p>(CARBONER, CARBONER 974F) (C - na - na - [na - na - na]),</p> <p>(POTASSIUM SODIUM MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - na - na - [na - na - na]),</p> <p>(SODIUM PICOSSULFATE) (C - na - na - [na - na - na]),</p> <p>Not reported</p>	C38		
EU-EC-1000872389	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunosuppressant - na - [na - na - na])	C38	
EU-EC-1000872004	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - Immunosuppressant])	C38	
EU-EC-1000872005	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - Immunosuppressant])	C38	
EU-EC-1000872007	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - 10PF - Immunosuppressant])	C38	
EU-EC-1000872008	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Hypertension (via - Unknown - Results in Death), Sense of oppression (via - Unknown - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawal - [na - 10PF - Immunosuppressant])	C38	
EU-EC-100089499	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	No	Death (via - Fatal - Results in Death), Block temperatures decreased (via - Fatal - Results in Death), Sense of oppression (via - Unknown - Results in Death), Bradycardia (via - Fatal - Results in Death), Cold sweat (via - Fatal - Results in Death), Cyanosis (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dyspnoea (via - Fatal - Results in Death), Hypertension (via - Fatal - Results in Death), Hypoxia (via - Fatal - Results in Death), Pain (via - Fatal - Results in Death), Vomiting (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10PF - na])	C38
EU-EC-100089476	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	No	Death (via - Fatal - Results in Death), Acute myocardial infarction (MI - Fatal - Results in Death), Death (MI - Fatal - Results in Death), Pulmonary oedema (MI - Fatal - Results in Death)	COMIRNATY COVID-19 mRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - Immunosuppressant - Not applicable - [na - 3mL - Immunosuppressant])	C38
EU-EC-100089412	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	C38	
EU-EC-100089405	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Diarrhoea (via - Unknown - Other Medically Important Condition), Melaena (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [na - na - na])	C38	
EU-EC-100089474	20/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])	C38
EU-EC-100089407	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	C38
EU-EC-100089470	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - Immunosuppressant])	C38	
EU-EC-100089479	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunosuppressant - Not applicable - [na - na - Immunosuppressant])	C38	
EU-EC-100089478	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 3mL - na - Male in ICSP])	C38	
EU-EC-100089423	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10PF - Immunosuppressant])	C38
EU-EC-100089496	20/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardiac arrest (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Pain in extremity (via - Not Recovered/Not Resolved -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - Immunosuppressant])	C38	
EU-EC-100087426	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	No	Death (via - Fatal - Results in Death), Haematuria (via - Unknown -), Road traffic accident (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - 10PF - na])	C38
EU-EC-100089499	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10PF - Immunosuppressant])	C38	
EU-EC-100089408	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10PF - Immunosuppressant])	C38	
EU-EC-100089472	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death), Melaena (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10PF - Immunosuppressant])	C38	
EU-EC-100089459	20/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Abdominal infection (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), General physical health deterioration (via - Fatal - Results in Death), Urinary tract infection (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	C38	
EU-EC-100089497	20/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Pneumonia (via - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Respiratory arrest (via - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Vaccination site pain (via - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	C38	
EU-EC-100089459	20/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Elderly	Male	No	Chills (via - Unknown -), Death (via - Fatal - Results in Death), Hypoxia (via - Unknown -), Melaena (via - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunosuppressant - na - [na - na - Immunosuppressant])	C38
EU-EC-100089413	20/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	No	Asthenia (via - Not Recovered/Not Resolved -), Death (via - Fatal - Results in Death), Hypoglycaemia (via - Not Recovered/Not Resolved -), Hypoxia (via - Not Recovered/Not Resolved -), Somnolence (via - Not Recovered/Not Resolved -), Vomiting (via - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunosuppressant - na - [na - na - Immunosuppressant])	C38
EU-EC-100089491	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Not Specified	Not Specified	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])	C38	
EU-EC-100089496	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Male	No	Crohn's colitis (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Respiratory distress (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	C38	
EU-EC-100089497	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Female	No	COVID-19 (S - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (S - Fatal - Results in Death), Drug ineffective (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Melaena (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])	C38	
EU-EC-100089430	20/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	COVID-19 (S - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Melaena (via - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	C38	
EU-EC-100089498	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - Immunosuppressant])	C38	
EU-EC-100089414	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	64-65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - Immunosuppressant])	C38	
EU-EC-100089496	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawal - [na - 10PF - Immunosuppressant])	C38	
EU-EC-100089423	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10PF - Immunosuppressant])	C38	
EU-EC-100089495	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10PF - Immunosuppressant])	C38	
EU-EC-100089492	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Diarrhoea (via - Fatal - Results in Death), General physical health deterioration (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])	C38	
EU-EC-100089405	20/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Asthenia (via - Not Recovered/Not Resolved - Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Diet related (via - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (via - Not Recovered/Not Resolved - Other Medically Important Condition), Gas instability (via - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (via - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (via - Not Recovered/Not Resolved - Other Medically Important Condition), Melaena (via - Not Recovered/Not Resolved - Other Medically Important Condition), Sedation (via - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (via - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	C38	
EU-EC-100089494	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Elderly	Male	No	Cardiovascular accident (via - Unknown - Other Medically Important Condition), Cone (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Disease recurrence (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	C38
EU-EC-100089494	20/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	64-65 Years	Not Specified	Male	No	Cough (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dyspnoea (via - Unknown -), Melaena (via - Unknown -), Myocardial infarction (via - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	C38	

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Country Regulatory Purpose	Literature Reference	Parent Age Group	Parent Sex	Parent Height (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])	CSR Form	
											[DIOCALCIFEROL] (C - na - na - [na - na - na]) [FLUCICANONE PROPIONATE] (C - na - na - [na - na - na]) [POLACACIN] (C - na - na - [na - na - na]) [FUROSEMIDE] (C - na - na - [na - na - na]) [LATANOPROST] (C - na - na - [na - na - na]) [LEVOTHYROXINE LEVOTHYROXINE SODIUM] (C - na - na - [na - na - na]) [RAMPRIL] (C - na - na - [na - na - na])		
EU-EC-100620026	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death), Respiratory distress (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - intramuscular])		CSR	
EU-EC-100620064	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Acute kidney injury (In - Unknown - Other Medically Important Condition), Death (In - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - na - na])		CSR	
EU-EC-100620065	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Aphasia (In - Fatal - Results in Death), Death (In - Fatal - Results in Death), Dyspnoea (In - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR	
EU-EC-100620799	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - [na - na - intramuscular])		CSR	
EU-EC-100620893	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death), Loss of consciousness (In - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR	
EU-EC-100620905	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Chest pain (In - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (In - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (In - Fatal - Results in Death), Hyperhidrosis (In - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypertension (In - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 3dL - intramuscular])	APIXARAN 5MG TABLET (C - na - na - [na - na - na]), NOT AVAILABLE (C - na - na - [na - na - na])	CSR	
EU-EC-100620928	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY COVID-19 mRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - na - na - [na - 3dL - intramuscular])		CSR	
EU-EC-100620963	18/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 1Df] - intramuscular)		CSR	
EU-EC-100620913	18/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (In - Fatal - Results in Death), Syncope (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - [na - na - intramuscular])	RELVAR ELIPTA [FLUTICASON FURATE, VILANTEROL] (C - Chronic obstructive pulmonary disease - na - [na - 1Df] - na), (AMODARONE, AMODARONE HYDROCHLORIDE) (C - Atrial fibrillation - na - [na - 200mg - na]), [BRISQODIL] (C - Constipation - na - [na - na - na]), [BURTANIDOL] (C - Constipation - na - [na - 1mg - na]), [LICTRINE DIIHYDROCHLORIDE] (C - Hypertension - na - [na - 10mg - na]), [DIOCALCIFEROL] (C - Vitamin D deficiency - na - [na - 2000IU] - na), [CYANOCOBALAMIN, HYDROXYCOBALAMIN] (C - Vitamin B12 deficiency - na - [na - 1mg - na]), [ENGRAFARN SODIUM] (C - Thrombosis prophylaxis - na -), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - na - [na - na - na]), [LACTULOSE, LACTULOSE LIQUID] (C - Constipation - na - [na - na - na]), [MORPHINE SULFATE, MORPHINE SULFATE PENTHYDRATE] (C - Cancer pain - na - [na - 10mg - Ona]), [OXAZEPAM] (C - Insomnia - na - [na - na - Ona]), [DIOXIDONE HYDROCHLORIDE] (C - Osteoarthritis, Pain - na -), [POTASSIUM CITRATE] (C - Hypokalaemia - na - [na - 600mg - na]), [POTASSIUM SODIUM MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - na - [na - 120] - na), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - na - [na - na - na]), [SODIUM PICOGLICATE] (C - Constipation - na - [na - na - na]), [SPRONOLACTONE] (C - Cardiac failure - na - [na - 25mg - na]), [ZOPICLONE] (C - Insomnia - na - [na - 7.5mg - na])		CSR
EU-EC-100620916	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - intramuscular])		CSR	
EU-EC-100620933	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Cold sweat (In - Unknown - Other Medically Important Condition), Death (In - Fatal - Results in Death, Other Medically Important Condition), Fever (In - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - na - na])		CSR	
EU-EC-100620952	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (In - Fatal - Results in Death), Fibromyalgia (In - Fatal - Results in Death), Syncope (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3dL - intramuscular])	[CENTRALINE, SIBUTRAMINE HYDROCHLORIDE] (C - na - na - [na - na - 100mg - na]) [PGOGLIFAZONE] (C - na - na - Not applicable - [na - 20mg - Ona]), (ACETYLSALICYLIC ACID) (C - na - Not applicable - [na - 100mg - Ona]), (ALLOPURINOL) (C - na - Not applicable - [na - 100mg - Ona]), (AMTRIFLUPIRIME HYDROCHLORIDE) (C - na - Not applicable - [na - 25mg - Ona]), (AMLODIPINE, AMLODIPINE BESILATE) (C - na - Not applicable - [na - 5mg - Ona]), (ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIPHOSPHATE) (C - na - Not applicable - [na - na - Ona]), (ATORVASTATIN, ATORVASTATIN CALCIUM) (C - na - Not applicable - [na - 10mg - Ona]), (DIOXAZEPAM) (C - na - Not applicable - [na - na - Ona]), (DIAZEPAM) (C - na - Not applicable - [na - 5mg - Ona]), (METHORMAN HYDROCHLORIDE) (C - na - Not applicable - [na - 500mg - Ona]), (PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUHYDRATE) (C - na - Not applicable - [na - 40mg - Ona]), (PANTOPRAZOLE, ZANTROPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUHYDRATE) (C - na - Not applicable - [na - na - Ona]), (PARACETAMOL, TRAMADOL, TRAMADOL HYDROCHLORIDE, PARACETAMOL) (C - na - Not applicable - [na - 1Df] - Ona), (ZOLPIDEM TARTRATE) (C - na - Not applicable - [na - 5mg - Ona]), NON SPECIFIED FATTY ACID (C - na - na - [na - na - na]), (METHORMAN HYDROCHLORIDE) (C - na - na - [na - na - na]), [ARELTO 15MG] (DIPHENHYDAMINE) (C - na - Dose not changed -)		CSR
EU-EC-100620974	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death, Other Medically Important Condition), Gastroenteritis (In - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - 1Df] - na)	(ACETYLSALICYLIC ACID) (C - Atrial fibrillation - Dose not changed - [na - 100mg - na]), (AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALATE) (C - Hypertension - Dose not changed - [na - 10mg - na]), (BETA-1 ADRENERGIC BLOCKERS) (C - Hypertension - na - [na - 1Df] - na), (DRY EXTRACT OF SIBBU SLOBA LEAVES (S547-1), EXTRACTOR SOLVENT: ACETONE 60% (M/L), GINMO SLOBA) (C - na - Dose not changed - [na - 160mg - na]), (PARACETAMOL) (C - Pharyngitis - na - [na - 3Df] - na), (TRIAZOLAM) (C - Insomnia - na -)		CSR
EU-EC-10062078488	18/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death), Pain in extremity (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - 1Df] - intramuscular)		CSR	
EU-EC-10062074917	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 1Df] - intramuscular)		CSR	
EU-EC-10062079486	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Cardiac arrest (In - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (In - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (In - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fulminant myocardial infarction (In - Fatal - Results in Death), Slin disorientation (In - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - na - na])	(AMLODIPINE, AMLODIPINE BESILATE) (C - na - na - [na - na - na]), (LEVOTHYROXINE LEVOTHYROXINE SODIUM) (C - na - na - [na - na - na]), (PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE) (C - Anxiety - na - [na - na - na]), [RAMPRIL] (C - na - na - [na - na - na])		CSR
EU-EC-10062079717	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - na])		CSR	
EU-EC-10062079947	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 3dL - intramuscular])		CSR	
EU-EC-10062079962	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [na - 1Df] - intramuscular)		CSR	
EU-EC-10062079965	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - 1Df] - intramuscular)		CSR	
EU-EC-10062079674	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - na])		CSR	
EU-EC-1006206800	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (In - Fatal - Results in Death), Face oedema (In - Unknown - Results in Death), Hypertension (In - Unknown - Results in Death), Oedema peripheral (In - Unknown - Results in Death), Pyrexia (In - Unknown - Results in Death), Tachycardia (In - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - 1Df] - intramuscular)		CSR	
EU-EC-1006206883	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - na])		CSR	
EU-EC-1006206670	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death, Other Medically Important Condition), Hypertensive crisis (In - Recovering/Resolving - Results in Death, Other Medically Important Condition), Tremor (In - Recovering/Resolving - Results in Death, Other Medically Important Condition), Vertigo (In - Recovering/Resolving - Results in Death, Other Medically Important Condition), Visual impairment (In - Recovering/Resolving - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 3dL - intramuscular])		CSR	
EU-EC-1006206467	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - na])		CSR	
EU-EC-10062064204	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - intramuscular])		CSR	
EU-EC-10062064279	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - na - [na - na - intramuscular])		CSR	
EU-EC-10062064627	16/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Coronavirus (In - Fatal - Results in Death), Death (In - Fatal - Results in Death), Dyspnoea (In - Fatal - Results in Death), Makéla (In - Fatal - Results in Death), Personality change (In - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR	
EU-EC-10062061887	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Blister enticed (In - Unknown -) Death (In - Fatal - Results in Death), Pain (In - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - na - na])		CSR	
EU-EC-10062061817	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - na])	[ALENDRONATE SODIUM] (C - na - na - [na - na - na]), [BUDESONIDE, BUDESONIDE COMBOLE] (C - na - na - [na - na - na]), [CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - na - na - [na - na - na])		CSR
EU-EC-10062061821	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death), Dyspnoea (In - Fatal - Results in Death), Pneumonia (In - Fatal - Results in Death), Vomiting (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - intramuscular])		CSR	
EU-EC-10062061861	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - intramuscular]) COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - na])	[BETA-1 ADRENERGIC BLOCKERS] (C - na - na - [na - na - na]), [ACACIC ACID, SUXICACIC ACID, IRON, FERROUS (II) GLUCONATE SALT COMPLEX, FERROUS (II) GLUCONATE SALT COMPLEX, POLYSACCHARIDE IRON COMPLEX] (C - na - na - [na - na - na]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - na - na - [na - na - na]), (GOSIPROFEN S MONTENAPATE, GOSIPROFEN MONONITRATE) (C - na - na - [na - na - na]), (INDINAVIR, INDINAVIR HYDROCHLORIDE) (C - na - na - [na - na - na]), (NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE) (C - na - na - [na - na - na]), (OXAZEPAM) (C - na - na - [na - na - na]), (PROFENOFEN) (C - na - na - [na - na - na]), (RANITIDINE SODIUM) (C - na - na - [na - na - na]), (ZOPICLONE) (C - na - na - [na - na - na])		CSR
EU-EC-10062062084	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - na])		CSR	
EU-EC-10062062573	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Acute myocardial infarction (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - na])		CSR	
EU-EC-10062064179	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Resuscitation (In - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation) Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - na])		CSR	
EU-EC-10062064187	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (In - Fatal - Results in Death), Dyspnoea (In - Fatal - Results in Death), General physical condition abnormal (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 1Df] - na)		CSR	
EU-EC-10062064192	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 1Df] - na)	NOT AVAILABLE (C - na - na - [na - 200mg - na]), NOT AVAILABLE (C - na - na - [na - 30mg - na]), NOT AVAILABLE (C - na - na - [na - 5mg - na]), NOT AVAILABLE (C - na - na - [na - 40mg - na]), [CALCIUM POLYSTYRENE SULFONATE] (C - na - na - [na - 1Df] - na)		CSR
EU-EC-10062064193	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 1Df] - na)	RIPIROXIBAN 10MG TABLET (C - na - na - [na - na - na]), [DIOCALCIFEROL] (C - na - na - [na - na - na]), [VITAMIN] (C - na - na - [na - na - na])		CSR
EU-EC-10062061874	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death), Diet refusal (In - Fatal - Results in Death), Pyrexia (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [na - na - na])		CSR	
EU-EC-10062061870	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (In - Fatal - Results in Death), Syncope (In - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - na])		CSR	
EU-EC-10062061877	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - na - na - [na - na - na])		CSR	
EU-EC-10062061899	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - na - na])	AWAYS [FLUTICASON FURATE] (C - na - na - [na - na - na]), BETA-1 ADRENERGIC BLOCKERS (C - na - na - [na - na - na]), COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - na - [na - na - na]), PRIVGEN [HUMAN NORMAL BRAINUCLOBULIN] (C - na - na - [na - na - na]), [OXAZEPAM] (C - na - na - [na - na - na]), [DIOXIFEN] (C - na - na - [na - na - na]), FUROSEMIDE, FUROSEMIDE SODIUM (C - na - na - [na - na - na]), LEVOPROMAZINE (C - na - na - [na - na - na]), LEVOTHYROXINE LEVOTHYROXINE SODIUM (C - na - na - [na - na - na]), MAGNESIUM OXIDE, MAGNESIUM OXIDE LIGHT (C - na - na - [na - na - na]), [PARACETAMOL] (C - na - na - [na - na - na]), [POTASSIUM CHLORIDE] (C - na - na - [na - na - na]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - na - na - [na - na - na]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - na - na - [na - na - na])		CSR
EU-EC-10062061872	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Asthma (In - Unknown -), Chills (In - Unknown -), Death (In - Fatal - Results in Death), Disorientation (In - Unknown -), Dyspnoea (In - Unknown - Other Medically Important Condition), Finger cold (In - Unknown -), Feeling cold (In - Unknown -), Hypohidrosis (In - Unknown -), Loss of consciousness (In - Unknown - Other Medically Important Condition), Makéla (In - Unknown -), Respiratory distress (In - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - na - na])		CSR	
EU-EC-10062061892	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1Df] - intramuscular)		CSR	
EU-EC-10062061891	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 1Df] - intramuscular)		CSR	
EU-EC-10062061893	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (In - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - 3dL - intramuscular])		CSR	
EU-EC-10062061892	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (In - Fatal - Results in Death), Lethargy (In - Unknown - Caused/Prolonged Hospitalisation), Metal taste changes (In - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [na - na - intramuscular])	AFYRIS [EYRETRACTAM] (C - Infection - na - [na - na - Ona]), LANTIS [BILACIN, CLASIDINE] (C - Tuberculosis - na - [na - 100L - Subcutaneous]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIPHOSPHATE] (C - Hyperlipidemia - na - [na - 40mg - Ona]), [CASBI] (C - Constipation - na - [na - 12.2mg - Ona]), [DIOCALCIFEROL] (C - Vitamin D deficiency - na - [na - 5000IU] - Ona)		CSR

EU Lead Number	EV Summary Report Date	Report Type	Primary Country	Primary Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex	Reaction Onset (Days)	Reaction PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chir - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/ Administered Drug List (Drug Chir - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
											[LANTANOPROST] (C - na - na - [na - na - na]), [PARACETAMOL] (C - na - na - [na - na - na]), [DIETHANNE QUETAPINE FUMARATE] (C - na - na - [na - na - na]), [SALBUTAMOL SALBUTAMOL SALFATE] (C - na - na - [na - na - na]), [SERTRALINE SERTRALINE HYDROCHLORIDE] (C - na - na - [na - na - na])	
EU-EC-100076038	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (na - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - na - na - [na - 3mL - intramuscular])	Not reported	CSR
EU-EC-100076435	05/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	Cardiac arrest (na - Unknown - Other Medically Important Condition), Chills (na - Unknown -), Death (na - Fatal - Results in Death, Other Medically Important Condition), Dehydration (na - Unknown -), Diarrhoea (na - Unknown -), Dyspnoea (na - Unknown -), Immunodeficiency (na - Unknown - Other Medically Important Condition), Neutrophylgia (na - Unknown -), Pyrexia (na - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	CSR
EU-EC-100076401	04/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 3mL - na - Made in KCRS])	Not reported	CSR
EU-EC-100077452	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])	Not reported	CSR
EU-EC-100077770	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100077779	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100077784	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - 3mL - intramuscular])	[NEMSTATIN] (C - na - na - [na - na - na]), [BENTAZAPINE] (C - na - na - [na - na - na]), [RISPERIDONE] (C - na - na - [na - na - na])	CSR
EU-EC-100077816	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - na])	Not reported	CSR
EU-EC-100078203	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 10DF - intramuscular])	Not reported	CSR
EU-EC-100078217	03/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	CSR
EU-EC-100078443	02/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	CSR
EU-EC-100078414	02/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - intramuscular])	Not reported	CSR
EU-EC-100078402	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100079639	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - na - na - [na - 25mg - na]), NSULIN ASPART (NSULIN ASPART) (C - na - na - [na - na - na]), ALENDRONATE SODIUM ALENDRONIC ACID (C - na - na - [na - 100 - na]), [AMIODIPINE, AMIODIPINE BESILATE, AMIODIPINE MALEATE, AMIODIPINE MESILATE] (C - na - na - [na - na - na]), [DOXICICLIN, DOXICICLIN CARBONATE] (C - na - na - [na - na - na]), [DOXICICLIN] (C - na - na - [na - na - na]), [INFLUENZA VIRUS] (C - na - na - [1d - na - na]), [LACTULOSE] (C - na - na - [na - na - na])	CSR
EU-EC-100078904	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100078933	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - 3mL - intramuscular])	Not reported	CSR
EU-EC-100078921	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	[KEPRRA (LEVETIRACETAM)] (C - Epilepsy - na - [na - 2.5mL - na]), [TOLVED SODIUM NISINACILUM] (C - Diabetes mellitus - na - [na - 140g - na]), [DOLORZALAZONE] (C - Muscular therapy - na - [na - 200mg - na]), [CLOPIDOGREL] (C - Thrombolytic prophylaxis - na - [na - 75mg - na]), [FENTANYL, FENTANYL CITRATE] (C - Pain - na - [na - 100g - na]), [GLYCOPYRROLUM BROMIDE, GLYCOPYRROLUM BROMIDE, NESTIGONAM METHYL SULFATE] (C - Always separate cholinesterase therapy - na - [na - 1mL - na]), [LANSOPRAZOLE] (C - Prophyllaxie agent gastrointestinal ulcer - na - [na - 30mg - na]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Metabolic disorder - na - [na - 50ug - na]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - na - [na - 10DF - na]), [BENTAZAPINE] (C - Depression - na - [na - 10mg - na]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - na - [na - 10mL - na])	CSR
EU-EC-100078840	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100074884	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100074893	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - intramuscular])	[TRALENTA (NIGLITIN)] (C - Diabetes mellitus - na - [na - na - na]), [ANTIFOL M COMPOUND, DIMETICONE, DIMETICONE, COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS SILICA, COLLOIDAL ANHYDROUS DIMETICONE 100G] (C - Fatigue - na - [na - na - na]), [BUPRENORFIN] (C - Pain - na - [na - na - na]), [FUROSEMIDE] (C - Swelling - na - [na - na - na]), [MACROGOL 400] (C - Constipation - na - [na - na - na]), [PARACETAMOL] (C - Pain - na - [na - na - na]), [ZINC] (C - Inflammation - na - [na - na - na]), [DIPLOLOLE] (C - Inflammation - na - [na - na - na])	CSR
EU-EC-100074929	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100074946	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	[TORSEMIDE] (C - na - na - [na - na - na])	CSR
EU-EC-100075936	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - intramuscular])	[ACETILSALICYLIC ACID] (C - na - na - [na - 75mg - na]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - na - na - [na - 20mg - na]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - na - na - [na - 20ug - na]), [NOCOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN SODIUM PHOSPHATE, THIAMINE HYDROCHLORIDE, NOCOTINAMIDE, PYRIDOXINE HYDROCHLORIDE] (C - na - na - [na - 10DF - na]), [OXAZEPAM] (C - na - na - [na - 5mg - na]), [SALBUTAMOL, SALBUTAMOL SALFATE] (C - na - na - [na - na - na]), [TIOTROPIUM, GLIDOLATE] (C - na - na - [na - na - na])	CSR
EU-EC-100073946	27/02/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	Not reported	CSR
EU-EC-100073912	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	Not reported	CSR
EU-EC-100074036	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	Not reported	CSR
EU-EC-100074038	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	[CARBIMAZOLE] (C - na - na - [na - 5mg - na]), [NACLOXOL] (C - na - na - [na - 60mg - na]), [OXAZEPAM] (C - na - na - [na - 5mg - na]), [PARACETAMOL] (C - na - na - [na - 500mg - na])	CSR
EU-EC-100074037	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	Not reported	CSR
EU-EC-100074167	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	Not reported	CSR
EU-EC-100074249	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	Not reported	CSR
EU-EC-100074287	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - intramuscular])	Not reported	CSR
EU-EC-100073796	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - 10DF - na])	[XARELTO 1.5 MG FILM COATED TABLETS (RIVAROXABAN)] (C - na - na - [na - na - na])	CSR
EU-EC-100072966	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [10DF - na])	[NOT AVAILABLE] (C - na - na - [na - na - na])	CSR
EU-EC-100073003	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	[BRINDOLAMIDE (BRINDOLAMIDE)] (C - na - na - [na - na - na]), [ACETILSALICYLIC ACID, ASPIRIN BP] (C - na - na - [na - 3mg - na]), [DIPYRIDAMOLE] (C - na - na - [na - 3mg - na]), [LANTANOPROST] (C - na - na - [na - na - na]), [TRACOL (TIMOLOL MALEATE)] (C - na - na - [na - na - na])	CSR
EU-EC-100073206	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - immunisation - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100073139	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	[ACETILSALICYLIC ACID, ASPIRIN BP] (C - na - na - [na - 75mg - na]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE] (C - na - na - [na - na - na]), [ATORVASTATIN] (C - na - na - [na - 20mg - na]), [BUMETANIDE] (C - na - na - [na - na - na]), [BICALUTAMIDE, ESTADIUM BICALUTAMIDE] (C - na - na - [na - na - na])	CSR
EU-EC-100072021	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - immunisation - na - [na - na - intramuscular])	[ELIQUIS (RIVAROXABAN)] (C - Pulmonary embolism - na - [na - 5mg - na]), [GLYCERYL TRINITRATE] (C - na - na - [na - na - na]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - na - na - [na - na - na]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Hypertension - na - [na - 50mg - na]), [OXAZEPAM] (C - na - na - [na - na - na]), [PARACETAMOL, PARACETAMOL, ASPARTAM] (C - na - na - [na - na - na]), [SALBUTAMOL, SALBUTAMOL SALFATE] (C - Chronic obstructive pulmonary disease - na - [na - na - Respiratory (na)])	CSR
EU-EC-100072030	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100072013	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100072191	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - immunisation - na - [na - na - intramuscular])	[ELIQUIS (RIVAROXABAN)] (C - Cardiac failure - na - [na - 2.5mg - na]), [ACETILSALICYLIC ACID] (C - Myocardial ischaemia - na - [na - 75mg - na]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Cardiac failure - na - [na - 40mg - na]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - na - [na - 500mg - na]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - na - na - [na - 75mg - na]), [POTASSIUM DIURETIC] (C - na - na - [na - 100mg - na]), [PRAMIPEXOL] (C - Cardiac failure - na - [na - 5mg - na])	CSR
EU-EC-100072208	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100072134	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100072207	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100072242	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100072242	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100072254	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100072212	25/02/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COMIRNATY (TOZINAMERAN) (S - na - na - [na - na - intramuscular])	Not reported	CSR
EU-EC-100070643	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100070644	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	CSR
EU-EC-100070629	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	Not reported	CSR

EU Local Number	EV Summary Report Date	Report Type	Primary Country Qualification	Primary Country Regulatory Authority	Literature Reference	Age Group	Sex	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)	CR Form		
EU-EC-1000748419	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748437	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Elderly	Not Specified	Female	No	Death (vs) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748483	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748509	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - Immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748514	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - Immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747939	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - COVID-19 prophylaxis - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747949	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Abdominal pain (vs) - Unknown - ; Anal haemorrhage (vs) - Unknown - ; Back pain (vs) - Recovered/Resolved - ; Blood pressure decreased (vs) - Unknown - Other Medically Important Condition); C-reactive protein increased (vs) - Unknown - Other Medically Important Condition); Corns (vs) - Unknown - Other Medically Important Condition); Death (vs) - Fatal - Results in Death); General physical health deterioration (vs) - Unknown - Other Medically Important Condition); Heart rate decreased (vs) - Unknown - Other Medically Important Condition); Malaria (vs) - Unknown - ; Oxygen saturation decreased (vs) - Recovered/Resolved - Other Medically Important Condition); Somnolence (vs) - Unknown - Other Medically Important Condition); Tachypnoea (vs) - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	ACEYLSALICYLIC ACID (C - vs) - vs - vs [vs] - vs - vs); HYDROXYCARBAMIDE (C - vs) - vs - vs [vs] - vs - vs); [BENAZOLAC, [BENAZOLAC, ENYTRAL, ENYTRAL] (C - vs) - vs - vs [vs] - vs - vs); [TOSSEMIDE SODIUM] (C - vs) - vs - vs [vs] - vs - vs)	C18
EU-EC-1000748016	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748033	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Elderly	Not Specified	Male	No	General physical condition abnormal (22) - Fatal - Results in Death	COMIRNATY (TOZINAMERAN) (S - Immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748037	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death); Fatigue (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - vs) - vs - vs [vs] - vs - vs]	Not reported	C18
EU-EC-1000748006	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748058	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death); Fatigue (vs) - Fatal - Results in Death); Hypertensive emergency (vs) - Recovered/Resolved - Other Medically Important Condition); Pain (14 - Unknown - Other Medically Important Condition); Rales (15 - Unknown -)	COMIRNATY (TOZINAMERAN) (S - vs) - vs - vs [vs] - vs - vs]	Not reported	C18
EU-EC-1000748006	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death); Productive cough (vs) - Fatal - Results in Death); Wheezing (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747738	31/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747335	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747313	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747406	30/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (23) - Fatal - Results in Death); Pyrexia (23) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747405	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (15) - Fatal - Results in Death); General physical health deterioration (5) - Fatal - Results in Death); Influenza like illness (5) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748170	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death); Pyrexia (vs) - Unknown - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	Not reported	C18
EU-EC-1000748191	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	Not reported	C18
EU-EC-1000748198	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (15) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	Not reported	C18
EU-EC-1000748095	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Body temperature increased (vs) - Fatal - Results in Death); Death (vs) - Fatal - Results in Death); Malaria (vs) - Fatal - Results in Death); Tremor (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748017	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748196	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000748017	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000747917	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (1) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	Not reported	C18
EU-EC-1000747140	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000745136	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000745231	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - vs) - vs - vs [vs] - vs - vs]	Not reported	C18
EU-EC-1000745292	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000745091	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (17) - Fatal - Results in Death, Other Medically Important Condition); Influenza like illness (17) - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Polytherapy - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000745607	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000746063	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	Not reported	C18
EU-EC-1000746068	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	Not reported	C18
EU-EC-1000746412	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death); Increased bronchial secretion (vs) - Fatal - Results in Death); Pyrexia (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [vs] - vs - vs]	Not reported	C18
EU-EC-1000744863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (vs) - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - vs) - vs - vs [vs] - vs - vs]	Not reported	C18
EU-EC-1000744864	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (vs) - Fatal - Results in Death, Life Threatening); Fatigue (vs) - Fatal - Results in Death, Life Threatening); Somnolence (vs) - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - vs) - vs - vs [vs] - vs - vs]	Not reported	C18
EU-EC-1000744882	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - vs) - vs - vs [vs] - vs - vs]	Not reported	C18
EU-EC-1000744823	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - vs) - vs - vs [vs] - vs - vs]	Not reported	C18
EU-EC-1000744810	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (15) - Fatal - Results in Death); General physical condition abnormal (15) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000744819	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (vs) - Fatal - Results in Death); General physical health deterioration (vs) - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - vs) [vs] - vs - vs]	Not reported	C18
EU-EC-1000744863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (vs) - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - vs) [vs] - vs - vs]	Not reported	C18

EU Local Number	EV Summary Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Race	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])	CSR Form
EU-EC-1000733635	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Potential Hospitalisation), Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Caused/Potential Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Potential Hospitalisation), Resuscitation (n/a - Fatal - Results in Death, Life Threatening, Caused/Potential Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000738986	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Meningitis (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000731844	08/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (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]), [COLICALCIFEROL, COLICEM, COLICALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 10PF - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - n/a - n/a - [n/a - 100ug - 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]), [NIFAFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000731207	07/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000730781	06/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BETHISA (MIRABEGRON) (C - n/a - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [n/a - n/a - n/a]), [ANALOPFENE, ANLOPFINE BESILATE, ANLOPFINE MALEATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [OPRIFLOXACIN, OPRIFLOXACIN HYDROCHLORIDE, OPRIFLOXACIN HYDROCHLORIDE MONOHYDRATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [COLICALCIFEROL, CYANOCOBALAMIN, ERODICALFEROL, RETINOL ACETATE, ERODICALFEROL, 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 HEMIHYDRATE] (C - n/a - Not applicable -), [FOLIC ACID] (C - n/a - Not applicable - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE, BIFIDOBACTERIUM (SPP)] (C - n/a - Not applicable -), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Not applicable -), [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]), [ROFECICONE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [OTIMAIN] (C - n/a - Not applicable -)	CSR
EU-EC-1000730829	06/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Adult	Male	No	Death (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	CSR
EU-EC-1000729816	05/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - Polypharmacy - n/a - [n/a - n/a - intramuscular])	Not reported	CSR
EU-EC-1000729106	04/01/2021	Spontaneous	Not Healthcare Professional	European Economic Area	Not available	More than 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 (TOZNAMERAN) (S - Polypharmacy - n/a - [n/a - n/a - intramuscular])	Not reported	CSR
EU-EC-1000729208	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - Polypharmacy - n/a - [n/a - n/a - intramuscular])	Not reported	CSR
EU-EC-1000729100	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-84 Years	Elderly	Female	No	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 (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - intramuscular])	Not reported	CSR