

EU Local Number	EV Gateway Reason Date	Report Type	Primary Source Country (or Regulatory Purpose)	Literature Reference	Patient Age Group	Patient Sex	Parent Child Report	Reaction List PT (Duration + Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100872796	21/05/2021	Spontaneous	Healthcare Professional	Not available	65-85 Years	Not Specified	Female	No	Reaction list (PT - Duration - Outcome - Seriousness Criteria): Blood pressure increased (n/a - Unknown - ), Caudex death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100872879	21/05/2021	Spontaneous	Non Healthcare Professional	Not available	Not Specified	Not Specified	Male	No	Reaction list (PT - Duration - Outcome - Seriousness Criteria): Asthma (n/a - Unknown - ), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - )	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100872961	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 5mL - Intramuscular])	[BUDESONIDE, FORMOTEROL, FLUMARATE DIHYDRATE, FORMOTEROL, FLUMARATE, BUDESONIDE] (C - n/a - Drug withdrawn - ), [GLYCERYL TRINITRATE] (C - n/a - [n/a - n/a - Transdermal]), [POVIDONE K25, THEOPHYLLINE, THEOPHYLLINE ANHYDROUS] (C - n/a - n/a - ), [SPRONOLACTONE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-100873040	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Body temperature increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100873290	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-100873161	21/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	No	Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - Results in Death, Other Medically Important Condition), Nausea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Peripheral vascular disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100873038	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	ARIPRAZOLE [ARIPRAZOLE] (C - n/a - n/a - )
EU-EC-100873736	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100871227	20/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Male	No	Chills (n/a - Unknown - ), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100871266	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Female	No	Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100871467	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Female	No	Death (n/a - Fatal - Results in Death), Erosion (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE, FORMOTEROL, FLUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL, FLUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [ESTRADIOL] (C - Hormone replacement therapy - n/a - [n/a - n/a - n/a]), [FLUXETINE, FLUXETINE 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]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a])
EU-EC-100871570	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100871570	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported
EU-EC-100871664	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported
EU-EC-100871736	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])
EU-EC-100873095	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death), Ventricular fibrillation (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-100869817	19/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100873050	19/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZNAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular])	[EXELON (RISPERIDONE)] (C - Vasomotor dementia - n/a - [n/a - 1DF] - Orally), [ACEYLSALICYLIC ACID] (C - Anticoagulant therapy - n/a - [n/a - 1DF] - Oral), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - n/a - [n/a - 1DF] - Oral), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - Transdermal]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 50mg - Oral])
EU-EC-100870096	19/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	No	Condition aggravated (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Eczema (n/a - Unknown - ), Respiratory disorder (n/a - Unknown - )	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-100870474	19/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (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]), [TOUCO SOLIDAR [INSULIN GLARGINE] (C - n/a - n/a - [n/a - 5mL - Subcutaneous]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - 10mg - Oral]), [COLECALCEROL] (C - n/a - n/a - [n/a - n/a - Oral]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - Oral]), [SINOPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 2.5mg - Oral]), [SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - 360ug - Oral])
EU-EC-100872769	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZNAMERAN] (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	Not reported
EU-EC-100870814	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Female	No	Death (n/a - Fatal - Results in Death), Hepatic function abnormal (n/a - Unknown - ), Neutropen progression (n/a - Unknown - ), Fungal with thrombosis (n/a - Recovered/Resolving - Other Medically Important Condition)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), FLUVESTRANT [FLUVESTRANT] (S - Hormone receptor positive breast cancer - Unknown - [n/a - n/a - n/a]), BIRANSE [PALBOCICLUB] (S - Hormone receptor positive breast cancer - Unknown - [n/a - n/a - n/a])	Not reported
EU-EC-100871036	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported
EU-EC-100869830	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	C-reactive protein increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	JANUVIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANTUS SOLOSTAR [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - Oral]), [ACEYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Oral]), [ALUMINUM HYDROXIDE GEL, UNIS] [MAGNESIUM CARBONATE, SODIUM CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE, SODIUM CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE GEL, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINUM HYDROXIDE GEL, 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 - n/a]), [CARBAMAZEPINE] (C - n/a - n/a - [n/a - n/a - Oral]), [CARBOMER, CARBOMER 874P] (C - n/a - n/a - [n/a - n/a - Oral]), [COLECALCEROL, CALCIUM, COLECALCEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESTRODIOL] (C - n/a - n/a - [n/a - n/a - Vaginal]), [FENTANYL] (C - n/a - n/a - [n/a - n/a - Transdermal]), [FLUTICASON PROPRIONATE, SALMETEROL, FLUTICASON PROPRIONATE, SALMETEROL, XINAFOATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - Sublingual]), [BUPROFEN, BUPROFEN SODIUM DIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [BUPROPION, BUPROPION SODIUM DIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [BIPHAZOLAN, BIPHAZOLAN] (C - n/a - n/a - [n/a - n/a - Oral]), [KETOPROFEN, KETOPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - Topical]), [LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE, METOPROLOL TARTRATE PH. EUR.] (C - n/a - n/a - [n/a - n/a - Oral]), [MOMETASONE FURATE, MOMETASONE FURATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Nasal]), [MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [ORPHENADRINE CITRATE, PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [OXVOCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [DIPYRIDAMOLE, DIPYRIDAMOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [PITIFENONE HYDROCHLORIDE, METAMIZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM SODIUM MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - Oral]), [PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE, PROCHLORPERAZINE MALEATE BP, PROCHLORPERAZINE MESLATE] (C - n/a - n/a - [n/a - n/a - Oral]), [QUETIAPINE] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], [VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-1008690219	18/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - )	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE, FORMOTEROL, FLUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL, FLUMARATE DIHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE] (C - Diarrhoea - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Reflux gastritis - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a])
EU-EC-100869056	18/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[INSULIN ASPART [INSULIN ASPART], [INSULIN HUMAN (RDN)], [INSULIN HUMAN (SOPHANE) (RDN)] (C - n/a - n/a - [n/a - n/a - n/a]), [JANUVIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACEYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - 75mg - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - 300mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESLATE] (C - n/a - n/a - [n/a - n/a - 10mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - 40mg - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - 500mg - n/a]), [VALSARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - 1DF] - n/a)
EU-EC-1008690110	18/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hemoglobin decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lymphoedema (n/a - Unknown - ), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown - ), Swelling (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-100869079	18/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Recovered/Resolving - )	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported
EU-EC-100869247	18/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-100869248	18/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Recovering/Resolving - ), Haematochezia (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Somnolence (n/a - Recovering/Resolving - )	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-100868835	17/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Male	No	Death (n/a - Fatal - Results in Death), Mental impairment (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-100869629	17/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Insomnia (n/a - Fatal - Results in Death), Thrombosis (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular])	JARDIANCE [EMPAFLIZON] (C - n/a - n/a - [n/a - n/a - Oral]), [DICYCLOFENAC POTASSIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [TIAMBUSIN HYDROCHLORIDE, DILTIAZEMIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [HARFARMAN SODIUM] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-1008697004	17/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (n/a - Fatal - Results in Death), Exposure to SARS-CoV-2 (n/a - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	[ACEYLSALICYLIC ACID] (C - Anticoagulation - n/a - [n/a - n/a - n/a]), [ALPRAZOLAM] (C - Dementia - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a]), [TIAPRIDINE, TIAPRIDINE HYDROCHLORIDE] (C - Dementia - n/a - [n/a - n/a - n/a])
EU-EC-100869537	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	No	Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-100869625	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Female	No	Brain death (n/a - Unknown - Other Medically Important Condition), Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-1008691626	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Iliac fossa ileus (n/a - Recovering/Resolving - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[EDOXAN [EDOXAN]] (C - n/a - n/a - [n/a - 30mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESLATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [LANDOPRAZOLE] (C - n/a - n/a - [n/a - 30mg - n/a])



EU Local Number	EV Gateway Report Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex	Patient Group (as reported)	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (via - Unknown - Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death), Vaccination failure (via - Unknown - Caused/Prolonged Hospitalisation)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - n/a - n/a])	[AMLODIPINE] (C - n/a - n/a - [via - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [via - n/a - n/a]), [FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [via - n/a - n/a]), [FORMOTEROL FLUMARATE, FORMOTEROL FLUMARATE DIHYDRATE] (C - n/a - n/a - [via - n/a - n/a]), [FOSFONPHIL SODIUM] (C - n/a - n/a - [via - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [via - n/a - n/a]), [METOPROLOL TARTRATE] (C - n/a - n/a - [via - n/a - n/a]), [PANTOPRAZOLE] (C - n/a - n/a - [via - n/a - n/a]), [SPRONOLACTONE] (C - n/a - n/a - [via - n/a - n/a]), [THEOPHYLLINE] (C - n/a - n/a - [via - n/a - n/a]), [TIOTROPOLIUM OXIDATE] (C - n/a - n/a - [via - n/a - n/a])	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal pain (via - Unknown - ), Asthma (via - Unknown - ), COVID-19 (via - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death), General physical health deterioration (via - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (via - Unknown - ), Oxygen saturation decreased (via - Recovered/Resolved - Caused/Prolonged Hospitalisation), PCO2 abnormal (via - Recovered/Resolved - Caused/Prolonged Hospitalisation), Renal failure (via - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sudden hearing loss (via - Unknown - Other Medically Important Condition), Tinnitus (via - Unknown - )	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SERENXA REPENS] (C - Prostatic disorder - n/a - [via - n/a - n/a])	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Mabiate (via - Unknown - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Fatigue (via - Not Recovered/Not Resolved - )	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (via - Not Recovered/Not Resolved - ), Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Cardiac discomfort (via - Unknown - ), Cough (via - Unknown - ), Death (via - Fatal - Results in Death), Dizziness (via - Unknown - ), Dyspnoea (via - Unknown - ), Performance status decreased (via - Unknown - ), Somnolence (via - Unknown - )	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Agitation (via - Unknown - ), Death (via - Fatal - Results in Death), Neuropsychiatric symptoms (via - Unknown - )	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death), Pulmonary embolism (via - Unknown - Other Medically Important Condition), Suspected COVID-19 (via - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	No known Program and Term newborns	Male	Yes	Death neonatal (via - Fatal - Results in Death), Maternal exposure during pregnancy (via - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Premature baby (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Transplacental])	[ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Supplementation therapy - n/a - [via - 1DP] - n/a), [ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - Pregnancy - n/a - [via - 1DP] - n/a), [CALCIUM CARBONATE, CALCIUM CARBONATE PH EUR] (C - Gastroesophageal reflux disease - n/a - [via - 500mg - n/a]), [FLUTICASON PROPRIONATE] (C - Hypersensitivity - n/a - [via - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [via - n/a - n/a]), [TRIMETHOPRIM] (C - Domestic n/a - [via - n/a - n/a])	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Aphasia (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (via - Unknown - Other Medically Important Condition), Fatigue (via - Unknown - Other Medically Important Condition), Gal inabity (via - Unknown - Other Medically Important Condition), Hypersomnia (via - Unknown - Other Medically Important Condition), Incontinence (via - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CLORAZEPATE, CLONIDINE, CLONIDINE BESILATE] (C - n/a - n/a - [via - 75mg - n/a]), [PRENOSOLONE] (C - n/a - n/a - [via - 5mg - n/a])	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000867381	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Cardio-respiratory arrest (0d - Fatal - Results in Death), Death (0d - Fatal - Results in Death), Tumour thrombosis (0d - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - n/a - n/a])	[ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Unknown - [via - n/a - n/a]), [BETAXOLOL HYDROCHLORIDE] (C - n/a - Unknown - [via - n/a - n/a]), [MESALAZINE] (C - n/a - Unknown - [via - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [via - n/a - n/a]), [POLYSACCHARIDE IRON COMPLEX] (C - n/a - Unknown - [via - n/a - n/a])	ICSR
EU-EC-1000867381	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest discomfort (via - Recovered/Resolved - ), Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000867381	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), General physical health deterioration (via - Fatal - Results in Death), Unresponsive to stimuli (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - n/a - n/a - [via - n/a - n/a])	[ELIQUIS] (APIXABAN) (C - n/a - n/a - [via - n/a - n/a]), [PIPERASA CLAZAPINE] (C - n/a - n/a - [via - n/a - n/a]), [CARBOMER, CARBOMER 900] (C - n/a - n/a - [via - n/a - n/a]), [LEVOTHYRONINE] (C - n/a - n/a - [via - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [via - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [via - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE MONOHYDRATE] (C - n/a - n/a - [via - n/a - n/a])	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Completed suicide (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Gun shot wound (via - Fatal - Results in Death)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 1 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disorientated (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Erosional distress (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Exposure via breast milk (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Failure to thrive (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic enzymes increased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rash (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Aneurysm (via - Unknown - Other Medically Important Condition), Cerebral haemorrhage (via - Unknown - Other Medically Important Condition), Coma (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Vascular anastomosis (via - Unknown - Other Medically Important Condition)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Fatigue (via - Fatal - Results in Death), General physical health deterioration (via - Fatal - Results in Death), Nausea (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - n/a - n/a - [via - n/a - Intramuscular])	[ELIQUIS] (APIXABAN) (C - n/a - n/a - [via - n/a - n/a]), [CHLOROZAZONE] (C - n/a - n/a - [via - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [via - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [via - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [via - n/a - n/a]), [RIMVASTATIN] (C - n/a - n/a - [via - n/a - n/a])	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Diarrhoea (via - Not Recovered/Not Resolved - ), Fatigue (via - Not Recovered/Not Resolved - ), Vomiting (via - Not Recovered/Not Resolved - )	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death), Loss of consciousness (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Asthma (via - Unknown - ), Condition aggravated (via - Unknown - ), Confusional state (via - Unknown - ), Death (via - Fatal - Results in Death), Diarrhoea (via - Unknown - ), Dyspnoea (via - Unknown - ), Fall (via - Unknown - ), Nack pain (via - Unknown - ), Pain (via - Not Recovered/Not Resolved - ), Parosmia (via - Unknown - ), Peripheral edema (via - Unknown - ), Pyrexia (via - Unknown - ), Spinal disorder (via - Unknown - ), Urinary retention (via - Unknown - Other Medically Important Condition)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYL SALICYLIC ACID] (C - n/a - n/a - [via - 100mg - n/a]), [ENALAPRIL MALEATE] (C - n/a - n/a - [via - 10mg - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [via - 15mg - n/a]), [MORPHINE, MORPHINE POLYSTYRENE-CO-DIVINYLBENZENE] SULFONATE, MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE, MORPHINE SULFATE PH EUR] (C - Spinal disorder - n/a - [via - 20mg - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUHYDRATE] (C - n/a - n/a - [via - 20mg - n/a]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [via - 10mg - n/a])	ICSR
EU-EC-1000867381	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Acute coronary syndrome (0d - Fatal - Results in Death), Death (0d - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - n/a - [via - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000867381	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death), Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - n/a - n/a])	[CICADIN] (MELATONIN) (C - n/a - Unknown - [via - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [via - n/a - n/a]), [COLECALCIFEROL] (C - n/a - Unknown - [via - n/a - n/a]), [DASIPAM] (C - n/a - Unknown - [via - n/a - n/a]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - Unknown - [via - n/a - n/a]), [EZETIMIBE] (C - n/a - Unknown - [via - n/a - n/a]), [FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - Unknown - [via - n/a - n/a]), [FOLIC ACID] (C - n/a - Unknown - [via - n/a - n/a]), [IRBESARTAN] (C - n/a - Unknown - [via - n/a - n/a]), [LORMETAZEPAM] (C - n/a - Unknown - [via - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [via - n/a - n/a]), [MOXONIDINE] (C - n/a - Unknown - [via - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [via - n/a - n/a]), [QUETIAPINE, QUETIAPINE FLUMARATE] (C - n/a - Unknown - [via - n/a - n/a]), [SOTALOL, SOTALOL HYDROCHLORIDE] (C - n/a - Unknown - [via - n/a - n/a]), [TAMBOLOLIN HYDROCHLORIDE] (C - n/a - Unknown - [via - n/a - n/a])	ICSR
EU-EC-1000867381	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	C-reactive protein increased (12d - Fatal - Results in Death), Death (12d - Fatal - Results in Death), Dyspnoea (12d - Fatal - Results in Death), General physical health deterioration (12d - Fatal - Results in Death), Oxygen saturation decreased (12d - Fatal - Results in Death), Pneumonia (12d - Fatal - Results in Death), Pyrexia (12d - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [via - n/a - n/a])	Not reported	ICSR
EU-EC-1000867381	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY [TOZNAMERAN] (S - Immunisation - n/a - [via - n/a - n/a])	Not reported	ICSR

EU Local Number	EVA Gateway Report Date	Report Type	Primary Source Country Regulatory Purposes Area	Primary Source Country Regulatory Purposes Area	Literature Reference	Patient Age Group	Patient Age Group (as reported)	Patient Sex	Patient Sex	Parent/Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100854438	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100854433	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	[ELQUIS (APXIBAN) (C - na - na - [na - na - na]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - na - na - [na - na - na]), [CANDESARTAN] (C - na - na - [na - na - na])	ICSR
EU-EC-100855916	05/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	No	Asthma (via - Not Recovered/Not Resolved - ), Death (via - Fatal - Results in Death), Decreased appetite (via - Not Recovered/Not Resolved - ), General physical health deterioration (via - Not Recovered/Not Resolved - ), Headache (via - Not Recovered/Not Resolved - ), Nausea (via - Not Recovered/Not Resolved - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1d] - Intramuscular)	Not reported	ICSR
EU-EC-100859296	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Cardiovascular accident (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [3d - 3d] - na - More in ICSR)	Not reported	ICSR
EU-EC-100859444	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), General physical condition abnormal (via - Unknown - Caused/Not Reported)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	Not reported	ICSR
EU-EC-100856079	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1d] - Intramuscular)	Not reported	ICSR
EU-EC-100853718	05/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death), Deep vein thrombosis (via - Unknown - Other Medically Important Condition), Feeling odd (via - Unknown - Caused/Not Reported), Hyperhidrosis (via - Unknown - Caused/Not Reported), Insomnia (via - Unknown - ), Pain in extremity (via - Unknown - ), Pyrexia (via - Unknown - ), Thrombosis (via - Unknown - Caused/Not Reported)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	ICSR
EU-EC-100853804	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [3d - 3d] - na)	[FENOTEROL, HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL, HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - na - na - ), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - na - ), [THEOPHYLLINE] (C - na - na - )	ICSR
EU-EC-1008538718	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100853979	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1008544510	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1d] - Intramuscular)	Not reported	ICSR
EU-EC-100854660	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d] - na)	NOT AVAILABLE (C - Ischaemic stroke - via - [na - 75mg - na]), NOT AVAILABLE (C - na - na - [na - 10mg - na])	ICSR
EU-EC-1008547979	05/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [3d - 1d] - na)	[FLAVIX (ELQIPROXIL, ELQIPROXEL, HYDROGEN SULFATE) (C - Thrombosis prophylaxis - via - [3d - 150mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - Hypertension - na - [3d - 10mg - Oral]), [BISACODYL] (C - Constipation - na - [3d - 10mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - na - [3d - 20mg - Oral]), [MORPHINE, HYDROCHLORIDE] (C - Pain - na - [3d - 10mg - Oral]), [MORPHINE SULFATE] (C - Pain - na - [3d - na - Oral]), [PARACETAMOL] (C - Pain - na - [3d - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - na - [3d - 750mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - na - [3d - 150F - Oral]), [VITAMIN D, CALCIUM] (C - Mineral supplementation - na - [3d - 1d] - Oral), [VITAMINS NDS] (C - Vitamin supplementation - na - [3d - 1d] - Oral)	ICSR
EU-EC-100852351	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Aspiration (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Myelodysplastic syndrome (via - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	[AZACITIDINE (AZACITIDINE) (C - Myelodysplastic syndrome - na - [na - na - na]), [POSACONAZOLE (POSACONAZOLE) (C - Myelodysplastic syndrome - na - [na - na - na]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - na - na - [na - 10mg - na]), [ERYTHROPIETIN] (C - Myelodysplastic syndrome - na - [na - 150ug - na]), [METOCLOPRAMIDE] (C - na - na - [na - na - na]), [OMEPRAZOLE] (C - Dyspepsia - na - [na - 10mg - na - More in ICSR]), [ONDANSETRON] (C - na - na - [na - na - na]), [PARACETAMOL] (C - na - na - [na - 4g - na]), [SOLFENACIN] (C - Hypertonic bladder - na - [na - 5mg - na]), [TRAMEXAMIC ACID] (C - Thrombocytosis - na - [na - 1500mg - na])	ICSR
EU-EC-100852449	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [3d - 3d] - Intramuscular)	Not reported	ICSR
EU-EC-100852567	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (14d - Fatal - Results in Death), General physical health deterioration (14d - Fatal - Results in Death), Inflammation (14d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	[LUXANA (EDOXABAN, EDOXABAN TOBYLATE) (C - na - Unknown - [na - na - na]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY MAGNESIUM] (C - na - Unknown - [na - na - na]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL, BISOPROLOL HEMIFUMARATE] (C - na - Unknown - [na - na - na]), [CALCIUM CITRATE] (C - na - Unknown - [na - na - na]), [COLECALCIFEROL] (C - na - Unknown - [na - na - na]), [DIGOXIN, DIGOXIN PH EUR] (C - na - Unknown - [na - na - na]), [DIONEPEL] (C - na - Unknown - [na - na - na]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - na - Unknown - [na - na - na]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - na - Unknown - [na - na - na]), [ACETYSALICYLIC ACID] (C - na - Unknown - [na - na - na]), [ASCORBIC ACID, CYANOCOBALAMIN, THIAMINE, IRON] (C - Renal disorder - via - [na - na - na]), [CARVEDILOL] (C - Hypertension - na - [3d - 3.125mg - na]), [CLONIDINE] (C - Hypertension - na - [3d - 1mg - na]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - Hypertension - na - [na - 4mg - na]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - na - [na - 5mg - na]), [BIRTAZAPINE] (C - Anxiety - na - [na - 15mg - na]), [PARACETAMOL] (C - Pain - na - [na - 500mg - na]), [SIMVASTATIN] (C - Cardiac disorder - na - [na - 10mg - na])	ICSR
EU-EC-100852538	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	No	Chest pain (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Injection site reaction (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	[HALOPERIDOL, HALOPERIDOL DECANOATE] (C - na - Unknown - [na - na - na]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - na - Unknown - [na - na - na]), [ACETYSALICYLIC ACID] (C - na - Unknown - [na - na - na]), [ASCORBIC ACID, CYANOCOBALAMIN, THIAMINE, IRON] (C - Renal disorder - via - [na - na - na]), [CARVEDILOL] (C - Hypertension - na - [3d - 3.125mg - na]), [CLONIDINE] (C - Hypertension - na - [3d - 1mg - na]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - Hypertension - na - [na - 4mg - na]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - na - [na - 5mg - na]), [BIRTAZAPINE] (C - Anxiety - na - [na - 15mg - na]), [PARACETAMOL] (C - Pain - na - [na - 500mg - na]), [SIMVASTATIN] (C - Cardiac disorder - na - [na - 10mg - na])	ICSR
EU-EC-100852629	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	ICSR
EU-EC-100852040	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Aphonia (via - Unknown - Disabling), Death (via - Fatal - Results in Death), Dysarthria (via - Unknown - Disabling), Guillain-Barre syndrome (via - Unknown - Disabling, Other Medically Important Condition), Hypoaesthesia (via - Unknown - Disabling), Muscular weakness (via - Unknown - Disabling)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	[DULOXETINE (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Anxiety - na - [na - 20mg - na]), [LUMIGAN (BIMOPROST) (C - Eye disorder - na - [na - na - na]), [ACETYSALICYLIC ACID] (C - Cardiac disorder - na - [na - 81mg - na]), [ASCORBIC ACID, CYANOCOBALAMIN, THIAMINE, IRON] (C - Renal disorder - via - [na - na - na]), [CARVEDILOL] (C - Hypertension - na - [3d - 3.125mg - na]), [CLONIDINE] (C - Hypertension - na - [3d - 1mg - na]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - Hypertension - na - [na - 4mg - na]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - na - [na - 5mg - na]), [BIRTAZAPINE] (C - Anxiety - na - [na - 15mg - na]), [PARACETAMOL] (C - Pain - na - [na - 500mg - na]), [SIMVASTATIN] (C - Cardiac disorder - na - [na - 10mg - na])	ICSR
EU-EC-100852922	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100852948	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), Fall (via - Unknown - Other Medically Important Condition), Loss of consciousness (via - Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100852709	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100852973	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Condition aggravated (via - Not Recovered/Not Resolved - ), Cystitis (via - Not Recovered/Not Resolved - ), Death (via - Fatal - Results in Death), Dyspnoea (via - Not Recovered/Not Resolved - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [3d - 3d] - Intramuscular)	[DIGOXIN] (C - na - na - [na - na - na]), [ISSORODINE (MONOTRATE, ISSORODINE MONOTRATATE) (C - na - na - [na - na - na]), [MELPERONE, MELPERONE HYDROCHLORIDE] (C - na - na - [na - na - na]), [METAZOLE, MAGNESIUM, METAZOLE SODIUM, METAZOLE SODIUM MONOHYDRATE] (C - na - na - [na - na - na]), [METOPROLOL, METOPROLOL TARTRATE] (C - Hypertension - na - [na - na - na]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - na - na - [na - na - na]), [PARACETAMOL] (C - na - na - [na - na - na]), [PERINDOPRIL, ARGININE] (C - Hypertension - na - [na - na - na]), [WARFARIN, WARFARIN SODIUM] (C - na - na - [na - na - na]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - na - na - [na - na - na])	ICSR
EU-EC-100853028	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100853169	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), Fatigue (via - Unknown - ), Headache (via - Unknown - ), Malaise (via - Unknown - )	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	[BENZONATATE] (C - na - na - [na - 300mg - Oral]), [NAPROXEN] (C - na - na - [na - 1000mg - Oral])	ICSR
EU-EC-100853302	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Bradycardia (via - Unknown - Other Medically Important Condition), Cardiovascular accident (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Fall (via - Unknown - Other Medically Important Condition), Gaze palsy (via - Unknown - Other Medically Important Condition), Hemiparesis (via - Unknown - Other Medically Important Condition), Ischaemic stroke (via - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (na - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Drug ineffective (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	[ACETYSALICYLIC ACID] (C - na - na - [na - 100mg - Oral]), [PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMHYDRATE] (C - na - na - [na - 1g - Oral])	ICSR
EU-EC-100853348	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	No	COVID-19 (na - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Oxygen saturation decreased (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	ICSR
EU-EC-100851283	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Acute respiratory distress syndrome (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dyspnoea (via - Fatal - Results in Death), Oxygen saturation decreased (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100851314	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - Not applicable - [na - na - na])	[FRESSIA (INSULIN DEGLUDEC) (C - na - na - ), [ACETYSALICYLIC ACID] (C - na - na - ), [AMLODIPINE, AMLODIPINE BESILATE] (C - na - na - ), [HYDROCHLOROTHIAZIDE, LISINAPRIL, HYDROCHLOROTHIAZIDE, LISINAPRIL ANHYDROUS, LISINAPRIL DIHYDRATE, HYDROCHLOROTHIAZIDE] (C - na - na - ), [LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - na - na - ), [PARACETAMOL, CODEINE PHOSPHATE HEMHYDRATE] (C - na - na - ), [ZOLPIDEM] (C - na - na - )	ICSR
EU-EC-100851328	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - Not applicable - [1d - na - na])	[BUPIRENORPHINE] (C - Pain - na - [na - 1d] - Cutaneous), [CARBOMER, CARBOMER 980] (C - Dry eye - na - [na - 3mg] - Ophthalmic), [LACTULOSE] (C - Constipation - na - [na - 20ml - Oral]), [PARACETAMOL] (C - Pain - na - [na - 1g - na]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Restlessness - na - [na - 25mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - na - [na - 20DF] - Oral), [VITAMIN D] (C - na - na - [na - 40ug - na])	ICSR
EU-EC-100851388	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	No	Confusional state (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Pyrexia (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - na - na - [1d - na - na])	Not reported	ICSR
EU-EC-100851743	03/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Fall (via - Unknown - Other Medically Important Condition), Loss of consciousness (via - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	[PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - na - na - [na - na - na]), [BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL, FUMARATE, BUDESONIDE] (C - na - na - [na - na - na]), [MONTELUKAST SODIUM] (C - na - na - [na - 10mg - na]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - na - na - [na - na - na]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - via - [na - na - na]), [SIMVASTATIN] (C - na - na - [na - na - na]), [ZOLPIDEM TARTRATE] (C - na - na - [na - 10mg - na])	ICSR
EU-EC-100851820	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Agonist (via - Unknown - ), Death (via - Fatal - Results in Death), Decreased appetite (via - Unknown - ), Diarrhoea (via - Unknown - ), Malaise (via - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	[ZOLPIDEM] (C - na - na - [na - na - na]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - na - na - [na - 10mg - na]), [ELQUIS (APXIBAN) (C - Anal sedation - na - [na - 10mg - Oral]), [FENTANYL, FENTANYL, FENTANYL CITRATE] (C - Pain - na - [na - na - Topical])	ICSR
EU-EC-100848804	3/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), Rash (via - Recovered/Resolved - Caused/Not Reported), Syncope (via - Recovered/Resolved - Caused/Not Reported)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	ICSR
EU-EC-100843047	3/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100849126	3/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100849189	3/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	[RIVAROXABAN (RIVAROXABAN) (C - na - na - ), [ALLOPURINOL] (C - na - na - ), [DIGOXIN, DIGOXIN PH EUR] (C - na - na - ), [METOPROLOL, METOPROLOL TARTRATE] (C - na - na - na - ), [SIMVASTATIN] (C - na - na - )	ICSR
EU-EC-100842262	3/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d] - [1d] - na)	NOT AVAILABLE (C - na - na - [na - na - na]), [NOVORAPD 100 EMAL, ORLOSSING VOOR INJECTIE IN FLACON, INSULIN ASPART] (C - na - na - [na - na - na]), [INSULIN ASPART, INSULIN DEGLUDEC] (C - na - na - [na - na - na]), [OMEPRAZOLE MAGNESIUM] (C - na - na - [na - na - na])	ICSR
EU-EC-100842512	3/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-100849181	3/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	ICSR
EU-EC-100849572	3/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [3d - 3d] - Intramuscular)	[ABASAGLAR (INSULIN GLARGINE) (C - na - na - ), [SOMEPRAZOLE (SOMEPRAZOLE) (C - na - na - ), [ACETYSALICYLIC ACID, DL-lysine ACETYSALICYLATE] (C - na - na - )	ICSR



EU Local Number	EV Gateway Report Date	Report Type	Primary Source Classification	Primary Source Country (as per Regulatory Purposes)	Literature Reference	Patient Age Group	Patient Sex	Patient Age Group (as per report)	Parent/Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-1000840703	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000840773	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000840348	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000841573	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cerebral haemorrhage (20 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-1000840225	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Fall (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000840378	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000840502	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	IRON (IRON) (C - Mineral supplementation - n/a - [n/a - n/a - n/a]), XAGRID (ANAGRELIDE, ANAGRELIDE HYDROCHLORIDE) (C - Blood disorder - n/a - [n/a - n/a - n/a]), [BETAMETHASONE, BETAMETHASONE VALERATE] (C - Wound treatment - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Pain - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [VITAMIN D, CALCIUM] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000837854	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	HYALOCAN (BIVAROZANIN) (C - n/a - n/a - [n/a - n/a - n/a]), [SILBOFIN, SILBOFIN] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [NIBVOLOL] (C - n/a - n/a - [n/a - n/a - n/a]), [NEMIPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIBSTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SIBVOZIC (BRUTINIB)] (C - n/a - n/a - [n/a - n/a - n/a]), [LANCOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [DULCAMETHAZOLE, BEMETHAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008381303	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	LUXIANA 15 MG FILM-COATED TABLETS (VALSARTAN, SACUBITRIL) (C - Cardiomopathy - Not applicable - [n/a - n/a - n/a]), LUXIANA 5 MG FILM-COATED TABLETS (VALSARTAN, SACUBITRIL) (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - Atrial fibrillation, Cardiomopathy - Not applicable - [n/a - n/a - n/a]), [EDOXAN] (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), [EFERENONE] (C - Cardiomopathy - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000838261	21/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	[LANCOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [DULCAMETHAZOLE, BEMETHAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), LUXIANA 15 MG FILM-COATED TABLETS (VALSARTAN, SACUBITRIL) (C - Cardiomopathy - Not applicable - [n/a - n/a - n/a]), LUXIANA 5 MG FILM-COATED TABLETS (VALSARTAN, SACUBITRIL) (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - Atrial fibrillation, Cardiomopathy - Not applicable - [n/a - n/a - n/a]), [EDOXAN] (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), [EFERENONE] (C - Cardiomopathy - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000838731	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000838849	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000838949	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000839056	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000840163	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	COVID-19 (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000835964	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000836903	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ESOMEPRAZOLE, ESOMEPRAZOLE SODIUM] (C - Dyspepsia - n/a - [n/a - 40mg - Oral]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 100mg - Oral]), [OXAZEPAM] (C - Emotional disorder - n/a - [n/a - 25mg - Oral])	ICSR
EU-EC-10008389703	20/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008389726	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000837305	20/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000837405	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Blood potassium increase (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FINASTERIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 400mg - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - 10mg - n/a]), [NEMIPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [DOXYCODONE, DOXYCODONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 20mg - n/a]), [DOXYCODONE, PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [PREDNISON] (C - n/a - n/a - [n/a - 1mg - n/a - More in ICSR]), [TAMSOLOSIN, TAMSOLOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - 2.5mg - n/a - More in ICSR])	ICSR
EU-EC-10008374451	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008378978	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1(Df) - n/a])	GLANZAPINE TEVA (GLANZAPINE) (C - Schizophrenia - n/a - [n/a - 5mg - Oral]), [REVICIA (PALPERIDONE PALMATE)] (C - Mental disorder - n/a - [n/a - 350mg - Intramuscular]), [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]), [THYROXINE] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008380328	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic aneurysm (n/a - Unknown - Other Medically Important Condition), Bacterial sepsis (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - ), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - ), Gastrointestinal infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - ), Mabixia (n/a - Recovered/Resolved - ), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - ), Nausea (n/a - Unknown - ), Off label use (n/a - Unknown - ), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - ), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vasculitis (n/a - Unknown - Other Medically Important Condition), Viral sepsis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthma (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	[ACEYLSALICYLIC ACID] (C - n/a - n/a - Dose not changed - [n/a - 100mg - n/a]), [COLICACIPROLOL, CALCIAM] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [FLUOREMBIDE, FLUOREMBIDE ECOSUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [METAMIZOL, METAMIZOL MONOHYDRATE] (C - n/a - n/a - [n/a - 350mg - n/a]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE, METOPROLOL TARTRATE PH. EUR] (C - n/a - n/a - Dose not changed - [n/a - 47.5mg - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [RETINOL, RETINOL PALMATE, DESIPANTHENDOL] (C - n/a - n/a - Dose not changed - [n/a - 300mg - n/a]), [ACEYLSALICYLIC ACID] (C - Myocardial ischaemia - 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]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYGLATE, 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]), [IPRATROPIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [NICOTANDOL] (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]), [TAMSOLOSIN, TAMSOLOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - n/a]), [DOPLOLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000838030	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal distension (n/a - Unknown - ), Cardiomegaly (n/a - Unknown - ), Condition aggravated (n/a - Unknown - ), Contusion (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)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACEYLSALICYLIC 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]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYGLATE, 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]), [IPRATROPIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [NICOTANDOL] (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]), [TAMSOLOSIN, TAMSOLOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - n/a]), [DOPLOLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008380301	19/04/2021	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), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008381463	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008382794	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008382603	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008382912	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Mabixia (n/a - Unknown - ), Secure (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008381487	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008383978	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008383894	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008315285	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Feeling hot (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - Other Medically Important Condition), Rash macular (n/a - Unknown - ), Throat oedema (n/a - Unknown - )	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACEYLSALICYLIC ACID] (C - Cardiovascular - n/a - [n/a - 87mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hyperlipidemia - n/a - [n/a - 20mg - Oral]), [DONESPEZ, HYDROCHLORIDE] (C - Demantia - n/a - [n/a - 5mg - Oral]), [ESZITALOPRAM OXALATE] (C - Depression - n/a - [n/a - 5mg - Oral]), [GABAPENTIN] (C - Pain - n/a - [n/a - 300mg - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [METOPROLOL, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [NAPROXEN SODIUM] (C - Pain - n/a - [n/a - 220mg - Oral]), [NEMIPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 325mg - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Abnormal behaviour, Demantia - n/a - [n/a - 250mg - Oral]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Pain - n/a - [n/a - 100mg - n/a])	ICSR
EU-EC-1000831398	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000831468	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Agitation (n/a - Unknown - ), Constipation abnormal (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Gal disturbance (n/a - Unknown - ), Halturination (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Intrusive thoughts (n/a - Unknown - ), Mabixia (n/a - Unknown - ), Muscle twitching (n/a - Unknown - ), Pallor (n/a - Unknown - ), Psychomotor hyperactivity (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - Other Medically Important Condition), Tachyphrenia (n/a - Unknown - ), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (25) - Recovered/Resolved - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 10mg - Oral]), [GLIMEPIRIDE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 100mg - Oral])	ICSR
EU-EC-1000831503	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Mabixia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19		



EU Local Number	EY Gateway Report Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group (as per report)	Patient Age Group	Patient Sex	Parent/Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-1000821659	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Whooping (n/a - Unknown - ). COVID-19 (44 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (30 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (45 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (46 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition).	COMIRNATY COVID-19 mRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZNAMERAN] (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-1000821870	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	HYDROCORTISONE (HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE) (C - n/a - n/a - [n/a - n/a - n/a]), OLEMESTINE, CLEMASTINE FUMARATE (C - n/a - n/a - [n/a - 1mg - n/a]), [DIAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [ECONAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESOMEPRAZOLE MAGNESIUM DRHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 300mg - n/a]), [LACTULOSE, LACTULOSE LIQUID] (C - n/a - n/a - [n/a - 20mL - n/a]), [MOMETASONE FURIOATE, MOMETASONE FURIOATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - n/a]), [SOXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [PROPIONAZINE, PROPIONAZINE MALEATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 10mg - n/a])	CSR
EU-EC-1000821855	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000821920	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 (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC 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]), [SERTRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [SCOLICALFEROL] (C - n/a - n/a - [n/a - 100mg - n/a]), [FLUTICASON PHRONATE, SALMETEROL] (C - n/a - n/a - [n/a - 100mg - n/a]), [SPRATROPOL BROMIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [TAMBULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a])	CSR
EU-EC-10008221973	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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - n/a)	[BRONCHODILATOR] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 100mg - n/a]), [SCOLICALFEROL] (C - n/a - n/a - [n/a - 100mg - n/a]), [FLUTICASON PHRONATE, SALMETEROL] (C - n/a - n/a - [n/a - 100mg - n/a]), [SPRATROPOL BROMIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [TAMBULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a])	CSR
EU-EC-10008223181	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Chills (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Respiratory rate increased (n/a - Unknown - ), Restlessness (n/a - Unknown - ), Syncope (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Influenza like illness (14 - Recovered/Resolved - ), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - n/a)	[ACETYSALICYLIC 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]), [SERTRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 100mg - n/a]), [SCOLICALFEROL] (C - n/a - n/a - [n/a - 100mg - n/a]), [FLUTICASON PHRONATE, SALMETEROL] (C - n/a - n/a - [n/a - 100mg - n/a]), [SPRATROPOL BROMIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [TAMBULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a])	CSR
EU-EC-1000822056	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Influenza like illness (14 - Recovered/Resolved - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BARRIDIN] (C - n/a - n/a - [n/a - n/a - n/a]), [XELKON (PALIPERIDONE PALMATATE)] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000822694	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), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [NOVOBURN 150 EMAL, CLOSING VOOOR INJECTIE IN FLACON, (INSULIN ASPART)] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000822629	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 (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000820951	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition).	COMIRNATY (TOZNAMERAN) (S - Phyllytes - n/a - [n/a - n/a - Intramuscular])	[NOVOBURN 150 EMAL, CLOSING VOOOR INJECTIE IN FLACON, (INSULIN ASPART)] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000820584	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition).	COMIRNATY (TOZNAMERAN) (S - Phyllytes - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000821001	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000821014	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[PRADAXA (DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE)] (C - Cardiovascular accident prophylaxis - n/a - [n/a - 110mg - Oral]), [BUMETANIDE] (C - Diuretic therapy - n/a - [n/a - 1mg - Oral]), [CYANOCOBALAMIN, HYDROXYCOBALAMIN] (C - Vitamin supplementation - n/a - [n/a - 1mg - Oral]), [FERROUS CHLORIDE TETRAHYDRATE, FERROUS ION] (C - n/a - n/a - [n/a - 9mg - 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 - 100mg - Oral]), [QUETIAPINE] (C - Posttemporal dementia - n/a - [n/a - 50mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea - n/a - n/a - [n/a - Respiratory (inhalation)])	CSR
EU-EC-1000821331	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Bedridden (21d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Hypophagia (21d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[XARELTO (RIVAROXABAN)] (C - n/a - n/a - ), [BUDESONIDE, BUDESONIDE, MICRONISED] (C - n/a - n/a - ), [DIONEPEZIL HYDROCHLORIDE] (C - n/a - n/a - ), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - ), [FUROSEMIDE] (C - n/a - n/a - ), [HYDROXYCOBALAMIN] (C - n/a - n/a - ), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - ), [MIRTAZAPINE] (C - n/a - n/a - ), [PARACETAMOL] (C - n/a - n/a - ), [POTASSIUM CHLORIDE] (C - n/a - n/a - ), [POTASSIUM SODIUM MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - ), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - ), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [40/17d - 40mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [50/5d - 0.5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [20/6d - n/a - n/a])	CSR
EU-EC-1000819333	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Secure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), White matter lesion (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - ), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [40/17d - 40mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [50/5d - 0.5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [20/6d - n/a - n/a])	CSR
EU-EC-1000819363	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Purpura (n/a - Fatal - Results in Death), Rash macular (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000819369	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Aspiration (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-1000819396	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000819479	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	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), Infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	[BRILIQUE (TCAGRESOR)] (C - n/a - n/a - [n/a - 90mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 50mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000819501	05/04/2021	Spontaneous	Healthcare Professional	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)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ATORVASTATIN] (C - Hypercholesterolemia - n/a - [n/a - n/a - n/a]), [SCOLICALFEROL, 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]), [VANCOMYCIN, VANCOMYCIN HYDROCHLORIDE] (C - Creative protein increased - n/a - [45d - n/a - n/a])	CSR
EU-EC-1000819597	05/04/2021	Spontaneous	Healthcare Professional	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 (1d - Fatal - Results in Death), Fatigue (n/a - Unknown - Life Threatening), Inappropriate schedule of product administration (n/a - Unknown - ), Malaise (n/a - Unknown - Life Threatening), Off label use (n/a - Unknown - )	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[VANCOMYCIN, VANCOMYCIN HYDROCHLORIDE] (C - Creative protein increased - n/a - [45d - n/a - n/a])	CSR
EU-EC-1000819352	04/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	[ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Dyslipidaemia - n/a - [n/a - 1] [DF] - Oral)	CSR
EU-EC-1000817642	03/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1] [DF] - Intramuscular)	Not reported	CSR
EU-EC-1000817664	03/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1] [DF] - Intramuscular)	Not reported	CSR
EU-EC-1000817061	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - Intramuscular)	Not reported	CSR
EU-EC-1000817118	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - Intramuscular)	Not reported	CSR
EU-EC-1000817171	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - Intramuscular)	Not reported	CSR
EU-EC-10008157160	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-10008193493	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10008160584	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	[AMLODIPINE] (C - n/a - n/a - [n/a - 10mg - n/a]), [ATENOLOL] (C - n/a - n/a - [n/a - 50mg - n/a]), [DESLORATADINE] (C - n/a - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - 5mg - n/a]), [AUSIBREN 30MG TABLET] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10008193637	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Arrhythmia (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Recovered/Resolved - ), Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Malaise (n/a - Unknown - ), Tachycardia (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - n/a)	[AMLODIPINE] (C - n/a - n/a - [n/a - 10mg - n/a]), [ATENOLOL] (C - n/a - n/a - [n/a - 50mg - n/a]), [DESLORATADINE] (C - n/a - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - 5mg - n/a]), [AUSIBREN 30MG TABLET] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000816384	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000816592	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	[CLOPIDOGREL] (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]), [ALLORUNOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [BUDESONIDE, FORMOTEROL, FLUMARATE DIHYDRATE, FORMOTEROL FLUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - 1] [DF] - n/a), [SCOLICALFEROL] (C - n/a - n/a - [n/a - 100mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [TIOTROPUM, TIOTROPUM BROMIDE, TIOTROPUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - 18ug - n/a])	CSR
EU-EC-10008147190	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000814480	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10008145133	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Decreased appetite (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Swelling face (n/a - Unknown - )	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10008145777	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [AMLODIPINE BESILATE, PERNAPRIL ANGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOPIDOGREL] (C - n/a - n/a - [n/a - 75mg - n/a]), [SCOLICALFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DIONEPEZIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 500mg - n/a]), [METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 300mg - n/a])	CSR
EU-EC-10008147073	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-10008147864	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - Intramuscular)	[PREGABALIN MYLAN 150 MG HARD CAPSULES (PREGABALIN)] (C - n/a - n/a - [n/a - n/a - n/a]), [VIFEND 200 MG FILM COATED TABLETS (VORICONAZOLE)] (C - n/a - n	







EU Local Number	EY Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Age Group (as per report)	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
										Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		MACROGOL 3350 (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 8DF] - Oral), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral - More in CSR]), [BENNA ALEXANDRINA LEAF, CASSIA] (C - n/a - n/a - [n/a - 8mg - Oral]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-1000805246	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Disease recurred (n/a - Unknown - Other Medically Important Condition), Cone (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-1000805104	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Disease recurred (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - ), Malaise (n/a - Unknown - ), Myocardial infarction (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LEVEMIR (INSULIN DETEMIR) (C - n/a - n/a - [n/a - n/a - n/a]), NOVOPARD (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-1000826208	23/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000826654	23/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-100082665	23/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Aphasia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000827096	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000827120	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	AZARGA (BRINZOLAMIDE, TIMOLOL, TIMOLOL MALEATE, BRINZOLAMIDE) (C - n/a - n/a - n/a - ), FENTANYL (FENTANYL, FENTANYL CITRATE) (C - n/a - n/a - [n/a - 25ug - n/a]), PROLIA (DENOSUMAB) (C - n/a - n/a - [n/a - 60mg - Subcutaneous]), [BISOPROLOL, BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - 400ug - n/a]), [LACTULOSE] (C - n/a - n/a - ), [LATANOPROST] (C - n/a - n/a - ), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1g - n/a]), [PRENISOLOLE] (C - n/a - n/a - [n/a - 5mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - 1mg - Respiratory Inhalation]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - Oral]), [ZOLPIDEM, ZOLPIDEM HEMITARTRATE, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 5mg - Oral])	
EU-EC-1000828393	23/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000829386	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Chest pain (20min - Recovered/Resolved - CausedProlonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death), Hyperkalemia (20min - Recovered/Resolved - CausedProlonged Hospitalisation), Hyperkalemia (n/a - Recovered/Resolved - CausedProlonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	APIXAN (SM TACR) (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000830538	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - CausedProlonged Hospitalisation), Pneumonia (n/a - Unknown - CausedProlonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-1000830208	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-1000799053	19/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000798103	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	RELVAR (ELIPTA) (FLUTICASON FURATE, VILANTEROL) (C - Chronic obstructive pulmonary disease - n/a - [n/a - 1DF] - n/a), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMODARONE, AMODARONE HYDROCHLORIDE] (C - Atrial fibrillation - n/a - [n/a - 200mg - n/a]), [BISACODYL] (C - Constipation - n/a - [n/a - n/a - n/a]), [BUMETANIDE] (C - Cardiac failure - n/a - [n/a - 1mg - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 2000IU - n/a]), [CYANOCOBALAMIN, HYDROXYCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - n/a]), [ENOXAPARIN SODIUM] (C - Thrombosis prophylaxis - n/a - ), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE LIQUID] (C - Constipation - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE] (C - Osteoarthritis - n/a - [n/a - 10mg - Oral]), [OXAZEPAM] (C - Insomnia - n/a - [n/a - n/a - Oral]), [OXYCODONE HYDROCHLORIDE] (C - Osteoarthritis, Pain - n/a - ), [OXAZEPAM] (C - Insomnia - n/a - [n/a - n/a - Oral]), [POTASSIUM CITRATE] (C - Hypokalaemia - n/a - [n/a - 600mg - n/a]), [POTASSIUM SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 15DF] - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - n/a - n/a]), [SPRONOLACTONE] (C - Cardiac failure - n/a - [n/a - 25mg - n/a]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - 7.5mg - n/a])	
EU-EC-10007982106	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000798209	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Cold sweat (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUPRENORPHINE] (C - n/a - n/a - [n/a - 10ug - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - 20mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [PIGLITAZONE] (C - n/a - n/a - [n/a - 30mg - Oral]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - Oral]), [AMTRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 10mg - Oral]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 500mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL, TRAMADOL, TRAMADOL HYDROCHLORIDE, PARACETAMOL] (C - n/a - n/a - [n/a - 1DF] - Oral), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 5mg - Oral])	
EU-EC-10008000575	19/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Nausea (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NON SPECIFIED STATINE (NOT AVAILABLE) (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [XARELTO 15 MG (RIVAROXABAN)] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10008000584	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)		CSR
EU-EC-10008000794	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Gastroenteritis (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - n/a)	[ACETYLSALICYLIC ACID] (C - Atrial fibrillation - Dose not changed - [n/a - 10mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - Hypertension - Dose not changed - [n/a - 10mg - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - Prophylaxis - n/a - [n/a - 10DF] - n/a), [DRY EXTRACT OF GINKGO BILOBA LEAVES (S-67)], EXTRACTIO SOLVENT: ACETONE 80% (M/M), GINKGO BILOBA] (C - n/a - Dose not changed - [n/a - 160mg - n/a]), [PARACETAMOL] (C - Prophylaxis - n/a - [n/a - 3DF] - n/a), [TRIAZOLAM] (C - Insomnia - n/a - )	
EU-EC-1000797464	19/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000797497	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000797480	19/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Fall (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Skin discoloration (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-1000797797	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007969497	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-1000796982	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000796986	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007966749	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000796690	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Face oedema (n/a - Unknown - Results in Death), Hypotension (n/a - Unknown - Results in Death), Oedema peripheral (n/a - Unknown - Results in Death), Pneumonia (n/a - Unknown - Results in Death), Tachycardia (n/a - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000796800	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007968270	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertensive crisis (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Tremor (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Vertigo (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Visual impairment (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007968467	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007947204	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007949379	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007949527	16/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Personality change (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007931887	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Bleat r (n/a - Fatal - Results in Death - Unknown - ), Death (n/a - Fatal - Results in Death), Pain (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007931817	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	[ALEDRONATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, BUDESONIDE MICRONISER] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007931821	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007931861	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]), COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	BETMIG (MIRABEGRON) (C - n/a - n/a - [n/a - n/a - n/a]), [ASORBIC ACID, SILICIC ACID, IRON, FERROUS (II) GLYCINE SULFATE COMPLEX, FERROUS (II) FERROUS (II) GLYCINE SULFATE COMPLEX, POLYSACCHARIDE IRON COMPLEX] (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]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007932284	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR

EU Local Number	EV Gateway Report Date	Report Type	Primary Source Country	Primary Source Country Regulatory Processes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Report	Reaction List PT (Duration / Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000793273	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation). Death (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation).	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000793470	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No Death (n/a - Fatal - Results in Death). Resuscitation (n/a - Fatal - Results in Death, Life Threatening, CausedProlonged Hospitalisation).	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000793487	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death). Dyspnoea (1d - Fatal - Results in Death). General physical condition abnormal (1d - Fatal - Results in Death).	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 200mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 30mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 80mg - n/a]).	CSR
EU-EC-1000793490	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death).	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - n/a])	[CALCIUM POLYSTYRENE SULFONATE] (C - n/a - n/a - [n/a - 1 [DF] - n/a]) NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), RIVAROXAN 15MG TABLET (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), VITAMIN D3 (C - n/a - n/a - [n/a - n/a - n/a]).	CSR
EU-EC-10007981674	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No Death (n/a - Fatal - Results in Death). Diet refusal (6d - Fatal - Results in Death). Pyrexia (n/a - Fatal - Results in Death).	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007981760	12/03/2021	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 - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007982077	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Syncope (3d - Recovered/Not Resolved - CausedProlonged Hospitalisation) 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-10007986099	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	AVAMY'S FLUTICASON FURATE (C - n/a - n/a - [n/a - n/a - n/a]), BETMIG (MIRABEGRON) (C - n/a - n/a - [n/a - n/a - n/a]), COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (C - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), PRIVIGEN (HUMAN NORMAL IMMUNOGLOBULIN) (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUCONAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOROTATORIS] (C - n/a - n/a - [n/a - n/a - n/a]), LEVOTHYRONINE LEVOTHYRONINE SODIUM (C - n/a - n/a - [n/a - n/a - n/a]), MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), SALBUTAMOL, SALBUTAMOL SULFATE (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]).	CSR
EU-EC-10007988757	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No Asthma (n/a - Unknown - ), Chills (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Discomfort (n/a - Unknown - ), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - ), Feeling odd (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mallaise (n/a - Unknown - ), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-10007989182	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1 [DF] - Intramuscular])	Not reported	CSR
EU-EC-10007988837	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - Intramuscular])	Not reported	CSR
EU-EC-10007988838	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3ml - Intramuscular])	Not reported	CSR
EU-EC-10007989672	11/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death), Lethargy (n/a - Unknown - CausedProlonged Hospitalisation), Mental status changes (n/a - Unknown - CausedProlonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	KEPPRA [LEVETIRACETAM] (C - Seizure - n/a - [n/a - 10ml - Oral]), LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 10U] - Subcutaneous), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hyperlipidaemia - n/a - [n/a - 40mg - Oral]), [CASSIA] (C - Constipation - n/a - [n/a - 17.2mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 5000IU] - Oral), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 40mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 1000mg - Oral]), [METOPROLOL SULCONATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 325mg - Oral]).	CSR
EU-EC-10007981400	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No Coma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypertonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007989196	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-100079892484	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No COVID-19 (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUCONAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYALURONATE, SODIUM HYALURONATE, CARBOMER 981] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYALURONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [GOSIRELIN] (C - n/a - n/a - [n/a - n/a - n/a]).	CSR
EU-EC-10007989380	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - n/a])	Not reported	CSR
EU-EC-10007989494	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DAYSODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a]).	CSR
EU-EC-100079894972	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3ml - Intramuscular])	Not reported	CSR
EU-EC-100079894973	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3ml - Intramuscular])	Not reported	CSR
EU-EC-100079895786	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No Cough (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - ), Lung infiltration (n/a - Unknown - ), Pneumonia (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	FLAVIN [LUPRODOL, CLOPIDOGREL HYDROGEN SULFATE] (C - Arteriosclerosis - n/a - [n/a - 75mg - Oral]), [ACETYSALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]), [AMLODIPINE BESILATE] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 1000IU] - Oral), [DOPAZOL HYDROCHLORIDE] (C - Demantia - n/a - [n/a - 10mg - Oral]), [FOLIC ACID] (C - Supplementation therapy - n/a - [n/a - 1mg - Oral]), [FLUCONAZOLE] (C - Oedema - n/a - [n/a - 20mg - Oral]), [GLUFENESIN] (C - Nausea/vomiting - n/a - [n/a - 30ml - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Demantia - n/a - [n/a - 20mg - Oral]), [METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 25mg - Oral]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastrooesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 650mg - Oral]), [POTASSIUM CHLORIDE] (C - Supplementation therapy - n/a - [n/a - 10g - Oral]), [PRAMIDONE] (C - Epilepsy - n/a - [n/a - 50mg - Oral]).	CSR
EU-EC-10007984237	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - Intramuscular])	Not reported	CSR
EU-EC-10007984640	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - Intramuscular])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Drug withdrawn - [n/a - 100mg] - Oral), [LOXAPINE] (C - n/a - Drug withdrawn - [n/a - 150mg] - Oral), [OXAZEPAM] (C - n/a - Drug withdrawn - [n/a - 50mg] - Oral), [PARACETAMOL] (C - n/a - Dose not changed - [n/a - 1 [DF] - Oral]).	CSR
EU-EC-100079875182	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - Intramuscular])	Not reported	CSR
EU-EC-10007976462	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No Death (n/a - Fatal - Results in Death). General physical condition abnormal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007977723	10/03/2021	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 - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007983357	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death), Mallaise (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - n/a])	HYDROXYCOBALAMIN (HYDROXYCOBAMIN) (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOPIN, LEVODOPA, LEVODOPA CARBOPIN MONOHYDRATE] (C - n/a - n/a - [n/a - 1 [DF] - n/a]), [GANFORT 0.3 MG/MG + 5 MG/MG, (MOLLI, MALEATE, BIMATOPROST)] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]).	CSR
EU-EC-10007984396	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 [DF] - n/a])	Not reported	CSR
EU-EC-10007982220	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported	CSR
EU-EC-10007982227	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported	CSR
EU-EC-10007984731	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death), Dyspepsia (n/a - Not Recovered/Not Resolved - Results in Death), Feeling hot (n/a - Not Recovered/Not Resolved - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - Oral]), LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - Oral]), LUMGAN [BIMATOPROST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SEQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [CARTILOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [BERCANDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [MACROGOL 4000] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]).	CSR
EU-EC-10007986134	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007986243	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3ml - n/a])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - ), [CARVEDILOL] (C - n/a - n/a - ), [SPRONOLACTONE] (C - n/a - n/a - ).	CSR
EU-EC-10007947608	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007948907	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007948934	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007949160	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007949421	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral]).	CSR
EU-EC-10007949887	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Oedema peripheral (n/a - Not Recovered/Not Resolved - ), Pyrexia (3d - Recovered/Not Resolved - ), Vomiting (2d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1 [DF] - Intramuscular])	EXFORGE [VALSARTAN, AMLODIPINE, VALSARTAN, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), ZYPERXA [180 COATED TABLET (ZINC) (ZINC)] (C - n/a - n/a - [n/a - 10mg - n/a]), [BISOPROLOL, FUMARATE, BISOPROLOL, HEXAMFURNATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [QUETIAPINE] (C - n/a - n/a - [n/a - 100mg - n/a]).	CSR
EU-EC-10007950198	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	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-10007950200	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No Arrhythmia (n/a - Unknown - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007950211	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No Disturbance in attention (n/a - Unknown - CausedProlonged Hospitalisation) Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007950212	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007950217	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No COVID-19 (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007950219	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No Death (n/a - Fatal - Results in Death), Respiratory distress (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	CSR
EU-EC-10007950221	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No Bedridden (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	CSR
EU-EC-10007950222	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No Death (n/a - Fatal - Results in Death), Chest pain (n/a - Not Recovered/Not Resolved - ), Death (n/a - Fatal - Results in Death), Gait instability (n/a - Not Recovered/Not Resolved - ), Quadriceps (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	CSR
EU-EC-10007950224	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	No Arrhythmia (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dysphonia (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation), Feeling odd (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR

EU Local Number	EV Gateway Report Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Group (as reported)	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000780226	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Asthma (via - Unknown - ), Chills (via - Unknown - ), Death (via - Fatal - Results in Death), Lethargy (via - Unknown - )	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780227	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (via - Fatal - Results in Death), Decreased appetite (via - Unknown - ), Dehydration (via - Not Recovered/Not Resolved - ), Diarrhoea (via - Not Recovered/Not Resolved - ), Gastrointestinal pain (via - Unknown - ), Nausea (via - Unknown - ), Oliguria (via - Not Recovered/Not Resolved - ), Pyrexia (via - Unknown - )	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intravenous (not otherwise specified))	Not reported	CSR
EU-EC-1000780228	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intravenous (not otherwise specified))	Not reported	CSR
EU-EC-1000780231	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intravenous (not otherwise specified))	Not reported	CSR
EU-EC-1000780235	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intravenous (not otherwise specified))	Not reported	CSR
EU-EC-1000780243	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780244	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780245	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Chronic kidney disease (via - Unknown - Caused/Not Resolved - ), Death (via - Fatal - Results in Death), Fall (via - Unknown - Caused/Not Resolved - ), Pyrexia (via - Unknown - )	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Subcutaneous)	Not reported	CSR
EU-EC-1000780255	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	15-64 Years	Adult	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780256	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (via - Fatal - Results in Death), Nausea (via - Not Recovered/Not Resolved - Caused/Not Resolved - )	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intravenous (not otherwise specified))	Not reported	CSR
EU-EC-1000780259	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	COVID-19 (via - Not Recovered/Not Resolved - ), Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000780261	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	COVID-19 (via - Not Recovered/Not Resolved - Caused/Not Resolved - ), Death (via - Fatal - Results in Death), Diarrhea (via - Not Recovered/Not Resolved - Caused/Not Resolved - ), Pyrexia (via - Not Recovered/Not Resolved - Caused/Not Resolved - )	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780264	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780271	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780271	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780273	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (via - Fatal - Results in Death), influenza like illness (via - Not Recovered/Not Resolved - )	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intravenous (not otherwise specified))	Not reported	CSR
EU-EC-1000780273	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-10007803156	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - n/a)	IBESARTAN 150 MG - TABLET (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [LORAZEPAM] (C - n/a - n/a - /n/a - n/a - n/a), [PAMPARONE] (C - n/a - n/a - /n/a - n/a - n/a), [RANITIDINE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE, TERBUTAFILIN BROMIDE MONOHYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [ENTERO 77] (N/A) (M) (C - n/a - n/a - /n/a - n/a - n/a), [JANUVA 50 MG FILM-COATED TABLETS (S) (S) (S) (S) (S) (S)] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780387	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (via - Fatal - Results in Death), Fatigue (via - Unknown - ), Muscular weakness (via - Unknown - )	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE, TERBUTAFILIN BROMIDE MONOHYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [ENTERO 77] (N/A) (M) (C - n/a - n/a - /n/a - n/a - n/a), [JANUVA 50 MG FILM-COATED TABLETS (S) (S) (S) (S) (S) (S)] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780388	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (via - Fatal - Results in Death), Diarrhea (via - Unknown - ), Injection site pain (via - Unknown - ), Nausea (via - Unknown - )	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE, TERBUTAFILIN BROMIDE MONOHYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [ENTERO 77] (N/A) (M) (C - n/a - n/a - /n/a - n/a - n/a), [JANUVA 50 MG FILM-COATED TABLETS (S) (S) (S) (S) (S) (S)] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780393	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	Blue toe syndrome (via - Unknown - ), Death (via - Fatal - Results in Death, Caused/Not Resolved - ), Feeling cold (via - Unknown - ), Heart rate increased (via - Unknown - Caused/Not Resolved - ), Myocardial infarction (via - Unknown - Caused/Not Resolved - ), Peripheral swelling (via - Unknown - ), Pneumothorax (via - Unknown - Caused/Not Resolved - ), Pyrexia (via - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - 1[d - n/a - n/a)	Not reported	CSR
EU-EC-1000780416	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [TOLTERODINE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [COLICALCEROL] (C - n/a - n/a - /n/a - n/a - n/a), [SODIUM VALPROATE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [SIRITAFILIN] (C - n/a - n/a - /n/a - n/a - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780294	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	15-64 Years	Adult	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [TOLTERODINE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [COLICALCEROL] (C - n/a - n/a - /n/a - n/a - n/a), [SODIUM VALPROATE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [SIRITAFILIN] (C - n/a - n/a - /n/a - n/a - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780300	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [TOLTERODINE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [COLICALCEROL] (C - n/a - n/a - /n/a - n/a - n/a), [SODIUM VALPROATE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [SIRITAFILIN] (C - n/a - n/a - /n/a - n/a - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780365	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - n/a - n/a)	NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [TOLTERODINE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [COLICALCEROL] (C - n/a - n/a - /n/a - n/a - n/a), [SODIUM VALPROATE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - /n/a - n/a - n/a), [SIRITAFILIN] (C - n/a - n/a - /n/a - n/a - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780375	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - 3mL - n/a)	[ATORVASTATIN, RYASTIGMINE] (C - n/a - n/a - /n/a - n/a - n/a), [BECLOMETHASONE DIPROPIONATE, FORMOTEROL, FLUMAZETIL, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FLUMAZETIL DIHYDRATE, BECLOMETHASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a - /n/a - n/a - n/a), [BUDESONIDE, FORMOTEROL, FLUMAZETIL, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FLUMAZETIL DIHYDRATE, BECLOMETHASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a - /n/a - n/a - n/a), [CARBOMER, CARBOMER 980] (C - n/a - n/a - /n/a - n/a - n/a), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - /n/a - n/a - n/a), [ESTRADIOL] (C - n/a - n/a - /n/a - n/a - n/a), [LATANOPROST] (C - n/a - n/a - /n/a - n/a - n/a), [MIRTAZAPINE] (C - n/a - n/a - /n/a - n/a - n/a), [PARACETAMOL] (C - n/a - n/a - /n/a - n/a - n/a), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - /n/a - n/a - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - /n/a - n/a - n/a), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - /n/a - n/a - n/a), NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780388	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - 3mL - Intramuscular)	NOT AVAILABLE (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000780838	05/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Cardiac arrest (via - Unknown - Other Medically Important Condition), Chills (via - Unknown - ), Death (via - Fatal - Results in Death, Other Medically Important Condition), Dehydration (via - Unknown - ), Diarrhoea (via - Unknown - ), Dizziness (via - Unknown - ), Immunodeficiency (via - Unknown - Other Medically Important Condition), Nausea/vomiting (via - Unknown - ), Pyrexia (via - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000779451	04/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 3mL - n/a - More in ICSR)	Not reported	CSR
EU-EC-1000777452	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	15-64 Years	Adult	Male	Aspiration (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000777709	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000777739	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-100077784	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (via - Fatal - Results in Death), Decreased appetite (via - Fatal - Results in Death), Diarrhoea (via - Fatal - Results in Death), Pyrexia (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - 3mL - Intramuscular)	[MEMANTINE] (C - n/a - n/a - /n/a - n/a - n/a), [MIRTAZAPINE] (C - n/a - n/a - /n/a - n/a - n/a), [RISPERIDONE] (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000779163	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000778023	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - Intramuscular)	Not reported	CSR
EU-EC-1000780217	02/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	COVID-19 (via - Unknown - Caused/Not Resolved - ), Condition aggravated (via - Unknown - ), Death (via - Fatal - Results in Death), Illness (via - Unknown - ), Mildness (via - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000776404	02/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Cerebrovascular accident (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Dyspnoea (via - Unknown - Other Medically Important Condition), Hypertension (via - Unknown - Other Medically Important Condition), Pneumonia (via - Fatal - Results in Death, Other Medically Important Condition), Renal failure (via - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - 1[d - n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780414	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Abdominal wall haemorrhage (via - Not Recovered/Not Resolved - Caused/Not Resolved - ), Abdominal wall haemorrhage (via - Not Recovered/Not Resolved - Caused/Not Resolved - ), Acute respiratory failure (via - Not Recovered/Not Resolved - Caused/Not Resolved - ), COVID-19 pneumonia (via - Not Recovered/Not Resolved - Caused/Not Resolved - ), Death (via - Fatal - Results in Death, Caused/Not Resolved - ), Hypertension (via - Not Recovered/Not Resolved - Caused/Not Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - 1[d - n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000780505	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000780579	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - /n/a - n/a - n/a)	Not reported	CSR
EU-EC-1000780693	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	15-64 Years	Not Specified	Male	Cardiac arrest (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - 1[d - n/a - n/a)	CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - n/a - n/a - /n/a - n/a - n/a), [INSULIN ASPART (INSULIN ASPART)] (C - n/a - n/a - /n/a - n/a - n/a), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - n/a - n/a - /n/a - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - /n/a - n/a - n/a), [DOLICACEROL, CALCIUM CARBONATE] (C - n/a - n/a - /n/a - n/a - n/a), [DOXUSATE] (C - n/a - n/a - /n/a - n/a - n/a), [INFLUENZA VIRUS] (C - n/a - n/a - /n/a - n/a - n/a), [LAMOTRIGINE] (C - n/a - n/a - /n/a - n/a - n/a), [LUPRIZOLAM] (C - n/a - n/a - /n/a - n/a - n/a), [SIBUTRAMINE SODIUM] (C - n/a - n/a - /n/a - n/a - n/a), [PERINDOPRIL, PERINDOPRIL ARGONINE] (C - n/a - n/a - /n/a - n/a - n/a), [TIAPRIDE, TIAPRIDE HYDROCHLORIDE] (C - n/a - n/a - /n/a - n/a - n/a), [VINPOCETINE] (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000779724	02/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - 3mL - Intramuscular)	[LUPRIZOLAM] (C - n/a - n/a - /n/a - n/a - n/a), [SIBUTRAMINE SODIUM] (C - n/a - n/a - /n/a - n/a - n/a), [PERINDOPRIL, PERINDOPRIL ARGONINE] (C - n/a - n/a - /n/a - n/a - n/a), [TIAPRIDE, TIAPRIDE HYDROCHLORIDE] (C - n/a - n/a - /n/a - n/a - n/a), [VINPOCETINE] (C - n/a - n/a - /n/a - n/a - n/a)	CSR
EU-EC-1000779804	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000779639	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - 3mL - Intramuscular)	Not reported	CSR
EU-EC-1000779021	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (via - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - /n/a - 1[DF] - Intramuscular)	KEPPRA (LEVETIRACETAM) (C - Epilepsy - n/a - /n/a - 2.5mL - n/a), TOUJEO SOLOSART (INSULIN GLARGINE) (C - Diabetes mellitus - n/a - /n/a - 14[U] - n/a), [CHLORZOXAZONE] (C - Muscle relaxant therapy - n/a - /n/a - 250mg - n/a), [CLOPIDOGREL] (C - Thrombosis prophylaxis - n/a - /n/a - 75mg - n/a), [FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - /n/a - 12ug - n/a), [GLYCOPYRROLIUM BROMIDE, GLYCOPYRROLIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - Airway secretion clearance therapy - n/a - /n/a - 1mL - n/a), [LANSOPRAZOLE] (C - Prophylaxis against gastrointestinal ulcer - n/a - /n/a - 30mg - n/a), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Metabolic disorder - n/a - /n/a - 50ug - n/a), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - /n/a - 100mg - n/a), [MIRTAZAPINE] (C - Depression - n/a - /n/a - 15mg - n/a), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - /n/a - 10mL - n/a)	CSR
EU-EC-1000774884	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Abdominal pain (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Dyspnoea (via - Fatal - Results in Death), Vomiting (via - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - /n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000774864	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (via - Fatal - Results in Death), General physical health deterioration (via - Fatal - Results in Death), Pneumonia (via - Fatal			

EU Local Number	EV Gateway Report Date	Report Type	Primary Source Qualification	Literature Reference	Patient Age Group	Patient Sex	Patient Age Group (as reported)	Parent Child Report	Reaction List PT (Duration ? 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)	ICSR Form
									Mabitis (n/a - Fatal - Results in Death), Muscle twitching (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyelonephritis (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), SARS-CoV-2 test negative (n/a - Fatal - Results in Death)		[MACRODOL 400] (C - Constipation - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - n/a - Oral])	
EU-EC-10007749029	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007749406	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[TORSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007751131	01/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cone (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug reflexes (n/a - Unknown - Other Medically Important Condition), Dyspnea (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Posturing (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - 5mg - n/a]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [CARVEDILOL HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - 3.125mg - n/a]), [COD-LIVER OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - Hypertension - n/a - [n/a - 1.25mg - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 40mg - n/a])	CSR
EU-EC-10007756396	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a]), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN SODIUM PHOSPHATE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1DF - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, OLODATEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [NOVOGRAPD [INSULIN ASPARTAR] (C - n/a - n/a - [n/a - n/a - n/a]), [TREBISA [INSULIN DEGLUCOSE] (C - n/a - n/a - [n/a - 30EU - n/a]), [ASCORBIC ACID, DRIED FERROUS SULFATE, ASCORBIC ACID, FERROUS SULFATE, ASCORBIC ACID, FERROUS SULFATE HYDRATE, DRIED FERROUS SULFATE] (C - n/a - n/a - [n/a - 300mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [CALCIUM CITRATE, MAIZE STARCH, STEARIC ACID, TALC, CALCIUM CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - 2mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - 1000mg - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a]), [TRIMETAZIDINE, DHYDROCHLORIDE] (C - n/a - n/a - [n/a - 36mg - n/a]), [VALSARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007756891	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	CSR
EU-EC-10007739446	27/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007739812	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007740366	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007740620	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	[CARBIMAZOLE] (C - n/a - n/a - [n/a - 5mg - Oral]), [NADOLOL] (C - n/a - n/a - [n/a - 40mg - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - Oral])	CSR
EU-EC-10007740627	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007741607	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Hypotension (n/a - Not Recovered/Not Resolved - Results in Death), Mabitis (n/a - Recovered/Resolved - Results in Death), Tachycardia (n/a - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007742409	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Recovered/Resolved - Results in Death), Hyperthermia (n/a - Not Recovered/Not Resolved - Results in Death), Lung disorder (n/a - Not Recovered/Not Resolved - Results in Death), Vaccination site inflammation (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007742671	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10007729795	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	[XARELTO 2.5 MG FILM-COATED TABLETS [BIVAROXAN]] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007729856	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007730000	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Chills (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mabitis (n/a - Unknown - ), Oedema peripheral (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Skin ulcer (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BRINZOLAMIDE [BRINZOLAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a - [n/a - 3mg - n/a]), [EPHYDRINAMIDE] (C - n/a - n/a - [n/a - 3mg - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [TMOLOL, TMOLOL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007732638	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007731130	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a - [n/a - 75mg - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007719978	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007720021	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Back pain (n/a - Unknown - ), Confusional state (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Dyspnea (n/a - Unknown - ), Hypertension (n/a - Unknown - )	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ELIQUIS [APIXABAN] (C - Pulmonary embolism - n/a - [n/a - 5mg - n/a]), [GLYCERYL TRINERATE] (C - n/a - n/a - ), [METOPROLOL, METOPROLOL HYDROCHLORIDE] (C - n/a - n/a - ), [METOPROLOL, METOPROLOL SUCCNATE, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [OXAZEPAM] (C - n/a - n/a - ), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - Respiratory (Inhalation)])	CSR
EU-EC-10007720390	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007720134	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007721191	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ELIQUIS [APIXABAN] (C - Cardiac failure - n/a - [n/a - 2.5mg - Oral]), [ACETYSALICYLIC ACID] (C - Myocardial infarction - n/a - [n/a - 75mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Cardiac failure - n/a - [n/a - 40mg - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 500mg - n/a]), [METOPROLOL, METOPROLOL SUCCNATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 750mg - Oral]), [RAMPRIL] (C - Cardiac failure - n/a - [n/a - 5mg - Oral])	CSR
EU-EC-10007722038	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007722134	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007722257	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007722482	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007723043	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007723054	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINERATE, GLYCERYL TRINERATE SOLUTION] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007731712	25/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10007730543	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Asthma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnea (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730544	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730723	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730928	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Abdominal pain (n/a - Unknown - ), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - ), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZNAMERAN [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-10007730971	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730721	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730490	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730862	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730875	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730879	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730876	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730925	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730927	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730949	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-10007730944	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000771838	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Aortic aneurysm rupture (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])	[BIMATOPROST [BIMATOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [CLOPIDDIGREL, CLOPIDDIGREL BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [FLEOPIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCORTISONE ACETATE, LIDOCAINE, LIDOCAINE, HYD	

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Classification	Primary Source Country Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Group (as per report)	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-1000771185	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - na - na - [na - 3ml - Intramuscular])	[PARACETAMOL] (C - na - na - [na - 1000mg - na]) TRIMBOW (BECLOMETHASONE DIPROPIONATE, GLYCOPYRRONIUM BROMIDE, FORMOTEROL FUMARATE DIHYDRATE) (C - na - na - [na - na - na]) [ACETYSALICYLIC ACID] (C - na - na - [na - 200mg - na]) [ACETYSALICYLIC ACID] (C - na - na - [na - 75mg - na]) [BISOPROLOL BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - na - na - [na - 2.5mg - na]) [CYANOCOBALAMIN] (C - na - na - [na - 1mg - na]) [ENALAPRIL ENALAPRIL MALEATE] (C - na - na - [na - 2.5mg - na]) [IPRATROPIUM IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - na - na - [na - na - na]) [EXXA [MEMANTINE HYDROCHLORIDE]] (C - na - na - [na - na - na]) [BISOPROLOL FUMARATE] (C - na - na - [na - na - na]) [FUROSEMIDE] (C - na - na - [na - na - na]) [SODIUM BICARBONATE] (C - na - na - [na - na - na]) [SODIUM BICARBONATE] (C - na - na - [na - na - na]) [SODIUM BICARBONATE] (C - na - na - [na - na - na])	ICSR
EU-EC-1000789372	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - na - na - [1d - na - Intramuscular])	[IPRATROPIUM IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - na - na - [na - na - na]) [EXXA [MEMANTINE HYDROCHLORIDE]] (C - na - na - [na - na - na]) [BISOPROLOL FUMARATE] (C - na - na - [na - na - na]) [FUROSEMIDE] (C - na - na - [na - na - na]) [SODIUM BICARBONATE] (C - na - na - [na - na - na]) [SODIUM BICARBONATE] (C - na - na - [na - na - na]) [SODIUM BICARBONATE] (C - na - na - [na - na - na])	ICSR
EU-EC-1000789377	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - na - na - [1d - na - Intramuscular])	Not reported	ICSR
EU-EC-1000789413	23/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death) Pulmonary oedema (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	Not reported	ICSR
EU-EC-1000789378	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789435	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789430	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - na])	[FOLIC ACID] (C - na - na - [na - na - na]) [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (C - Gouty arthritis - Not applicable - [na - na - na]) [PREDNISONE] (C - na - na - [na - na - na]) [DONEPEZIL, DONEPEZIL HYDROCHLORIDE] (C - Dementia Alzheimer's type - na - [na - 10mg - Oral]) [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - na - [na - 25mg - Oral])	ICSR
EU-EC-1000790922	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death) Decreased appetite (via - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000789328	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (via - Fatal - Results in Death) Fatigue (via - Unknown - Results in Death) Spasms (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	Not reported	ICSR
EU-EC-1000789328	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789454	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789786	23/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - Intramuscular])	Not reported	ICSR
EU-EC-1000789504	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Corns (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Disturbance in attention (via - Fatal - Results in Death), Peripheral vascular disorder (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - Intramuscular])	[CLOPIDOGREL] (C - na - na - [na - na - na]) [ENTRESTO [VALSARTAN, SACUBITRIL]] (C - na - na - [na - na - na]) [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - na - na - [na - na - na]) [PREDNISONE] (C - na - na - [na - na - na]) [TORSEMIDE] (C - na - na - [na - na - na])	ICSR
EU-EC-10007877192	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Vomiting (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007877199	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000787877	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000789410	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Aspiration (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Epilepsy (via - Fatal - Results in Death), Seizure (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789376	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000789435	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 1DF] - Intramuscular), [OXAZEPAM] (S - Anxiety - Not applicable - [na - 10mg - Oral])	Not reported	ICSR
EU-EC-1000789483	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death, Life Threatening), Racial haemorrhage (via - Unknown - Results in Death, Life Threatening)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000789504	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000789620	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death), Fatigue (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - na - na - [2d - na - Intramuscular])	[FUROSÉMIDE] (C - Cardiac failure - na - [10d - na - Intravenous (not otherwise specified)])	ICSR
EU-EC-1000789729	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007897405	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007897553	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789316	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789383	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898406	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898405	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898518	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898300	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-1000789806	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898096	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898170	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898247	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898325	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898361	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007898074	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Heart rate decreased (via - Unknown - ), Purplish coldness (via - Unknown - ), Syncope (via - Recovered/Resolved - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 1DF] - na), [FENTANYL] (S - Pain - Dose not changed - [na - 1DF] - na)	EXFORGE 5 MG/80 MG FILM COATED TABLETS [VALSARTAN, AMLODIPINE] (C - na - na - [na - na - na]), NOT AVAILABLE (C - na - na - [na - na - na]), [ALUMINIUM OXIDE, MAGNESIUM HYDROXIDE] (C - na - na - [na - na - na]), [FENTANYL, FENTANYL CITRATE] (C - na - na - [na - na - na]), [PARAFEN] (C - na - na - [na - na - na]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - na - na - [na - na - na]), [THIAMINE HYDROCHLORIDE, DECFANTHENYL, NICOTINAMIDE, NIHOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - na - na - [na - na - na]), [VASSLINE] (C - na - na - [na - na - na])	ICSR
EU-EC-10007891931	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007891981	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007895887	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - na - na - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007897863	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Mebesic (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - 3ML - Intramuscular])	[ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A CARTRIDGE (INSULIN GLARGINE)] (C - Diabetes - na - [na - 6U] - Subcutaneous), [FLURIDIONE] (C - Arrhythmia - na - [na - na - Oral]), [FUROSÉMIDE] (C - Cardiac failure - na - [na - 1DF] - Oral), [MACROGOL 4000] (C - Constipation - na - [na - 1DF] - Oral), [OMEPRAZOLE] (C - Gastric ulcer - na - [na - 1DF] - Oral), [PARACETAMOL] (C - Osteoarthritis - na - [na - 2DF] - Oral), [PAROXETINE] (C - Depression - na - [na - 1DF] - Oral), [RISPERIDONE] (C - Dementia - na - [na - 5mg - Oral]), [ACETYSALICYLIC ACID] (C - Myocardial ischaemia - na - [na - na - na]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Myocardial ischaemia - na - [na - na - na]), [ATORVASTATIN] (C - Myocardial ischaemia - na - [na - na - na]), [BENROFLUMETHAZIDE] (C - Hypertension - na - [na - na - na]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - na - [na - na - na])	ICSR
EU-EC-10007903966	17/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - na - na])	[RISPERIDONE] (C - Dementia - na - [na - 5mg - Oral]) [ACETYSALICYLIC ACID] (C - Myocardial ischaemia - na - [na - na - na]) [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Myocardial ischaemia - na - [na - na - na]), [ATORVASTATIN] (C - Myocardial ischaemia - na - [na - na - na]), [BENROFLUMETHAZIDE] (C - Hypertension - na - [na - na - na]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - na - [na - na - na])	ICSR
EU-EC-1000793370	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Vomiting (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	[APIXABAN (APIXABAN)] (C - na - na - na - [na - 2.5mg - Oral]), [FENTANYL, FENTANYL CITRATE] (C - na - na - [na - na - na] - Amg - Transdermal), [PREGABALIN (PREGABALIN)] (C - na - na - [na - 150mg - Oral]), [FUROSÉMIDE] (C - na - na - [na - 40mg - Oral]), [METAMIZOLE, METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM] (C - na - na - [na - 500mg - na]), [RAMPRIL] (C - na - na - [na - 5mg - Oral]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - na - na - [na - 5mg - Oral])	ICSR
EU-EC-10007939513	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Acute kidney injury (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ilex paralytic (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Microcytic anaemia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	[TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - na - na - [na - 5mg - Oral])	ICSR
EU-EC-10007939530	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Blood pressure decreased (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Body temperature increased (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death), Heart rate decreased (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - na - Not applicable - [na - 1DF] - na)	[DULOXETINE (DULOXETINE)] (C - na - na - ), [ESOMEPRAZOLE (ESOMEPRAZOLE)] (C - na - na - ), [NEUPRO (ROTIGOTINE)] (C - na - na - ), [ACENOCUMAROL] (C - na - na - ), [CARVEDILOL] (C - na - na - ), [FLUTICASON PROPRIONATE, SALMETEROL] (C - na - na - ), [FUROSÉMIDE, FUROSÉMIDE SODIUM] (C - na - na - ), [GABAPENTIN] (C - na - na - ), [SPIRONOLACTONE] (C - na - na - )	ICSR
EU-EC-10007939674	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - na - [na - na - Intramuscular])	Not reported	ICSR
EU-EC-10007943387	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007943445	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - na - [na - na - na])	Not reported	ICSR
EU-EC-10007947256	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Heart rate decreased (via - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [na - na - Intramuscular])	[KEPPRA [LEVETIRACETAM]] (C - Epilepsy - na - [na - 1500mg - Oral]), [LANTUS (INSULIN GLARGINE)] (C - Diabetes mellitus - na - [na - 32U] - Subcutaneous), [LURASIDONE HYDROCHLORIDE (LURASIDONE HYDROCHLORIDE)] (C - Schizophrenia - na - [na - 120mg - Oral]), [ACETYSALICYLIC ACID] (C - Cardiac disorder - na - [na - 81mg - Oral]), [ATENLOLOL, ATENLOLOL BP] (C - Essential hypertension - na - [na - 25mg - Oral]), [ATORVASTATIN CALCIUM] (C - Hyperlipidaemia - na - [na - 40mg - Oral]), [FINASTERIDE] (C - Benign prostatic hyperplasia - na - [na - 5mg - Oral]), [HALOPERIDOL] (C - Schizophrenia - na - [na - 10mg - Oral]), [HYPPROMELLOSE, GLYCEROL, MACROGOL 400, POLYVINYL ALCOHOL, PROPYLENE GLYCOL, VASELINE, LIQUID PARAFFIN] (C - Dry eye - na - [na - 400g] - Ophthalmic), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - na - [na - 88ug - Oral]), [LITHIUM CARBONATE] (C - Schizophrenia - na - [na - 900mg - Oral]), [OXAZEPAM] (C - Anxiety, Restlessness - na - [na - 1mg - Oral]), [LOSARTAN POTASSIUM] (C - Hypertension - na - [na - 25mg - Oral]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - na - [na - 20mg - Oral]), [PARACETAMOL] (C - Pain - na - [na - 3000mg - Oral]), [SERTRALINE HYDROCHLORIDE] (C - Depression - na - [na - 200mg - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - na - [na - 8mg - Oral]), [VITAMIN D] (C - Supplementation therapy - na - [na - 2000IU] - Oral)	ICSR
EU-EC-10007925788	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chest discomfort (via - Unknown - Results in Death), Death (via - Fatal - Results in Death), Vertigo (via - Unknown - Results in Death), Vomiting (via - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [na - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007926821	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly						

EU Local Number	EV Gateway Report Date	Report Type	Primary Source Classification	Primary Source Country (as reported)	Literature Reference	Patient Age Group	Patient Sex	Patient Group (as reported)	Parent/Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form	
												(BISOPROLOL FUMARATE) (C - n/a - n/a - [n/a - 2.5mg - n/a]), (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - 8mg - n/a]), (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - n/a - n/a - [n/a - 75mg - n/a]), (ECONAZOLE NITRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (FERROUS SULFATE) (C - n/a - n/a - [n/a - 1DF] - n/a), (METFORMIN, METFORMIN HYDROCHLORIDE) (C - n/a - n/a - [n/a - 500mg - n/a]), (PANTOPRAZOLE) (C - n/a - n/a - [n/a - 20mg - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000793619	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000793814	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - )	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000791826	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intra-muscular])	Not reported	ICSR	
EU-EC-1000791981	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intra-muscular])	(BISOPROLOL FUMARATE) (C - n/a - n/a - [n/a - 2.5mg - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - 1DF] - n/a), (FUROSEMIDE) (C - n/a - n/a - [n/a - 40mg - n/a]), (FUROSEMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (HYDROCHLOROTHIAZIDE) (C - n/a - n/a - [n/a - 25mg - n/a]), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - 75ug - n/a]), (MIRTAZAPINE) (C - n/a - n/a - [n/a - n/a - n/a]), (OMEPRazole) (C - n/a - n/a - [n/a - 20mg - n/a]), (OXAZEPAM) (C - n/a - n/a - [n/a - 5mg - n/a]), (OXAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a]), (OXYCODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 10mg - n/a]), (OXYCODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 20mg - n/a]), (OXYCODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 5mg - n/a]), (OXYCODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - n/a - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (SODIUM PICOSULFATE, SODIUM PICOSULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (SPRINOLACTONE) (C - n/a - n/a - [n/a - 50mg - n/a])	ICSR	
EU-EC-1000792070	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Lividly (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intra-muscular])	Not reported	ICSR	
EU-EC-1000792336	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intra-muscular])	Not reported	ICSR	
EU-EC-1000792257	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Blood pressure immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Swallow sounds (n/a - Unknown - ), Choking (n/a - Unknown - ), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Recovered/Resolved - ), Oxygen saturation immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1DF] - n/a)	(LORATADINE) (C - Drug hypersensitivity - n/a - [n/a - 10mg - n/a])	ICSR	
EU-EC-1000791817	14/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intra-muscular])	(DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE) (C - Cough - n/a - [n/a - 100mg - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - Cough - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR	
EU-EC-1000791787	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Subsida (n/a - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000796807	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000796820	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000796920	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-10007989120	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-10007989407	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Arrhythmia (n/a - Unknown - Results in Death), Cardiovascular accident (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000794197	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000794275	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000794346	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000794775	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intra-muscular])	Not reported	ICSR	
EU-EC-1000795768	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intra-muscular])	Not reported	ICSR	
EU-EC-1000796076	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Gaze palsy (n/a - Fatal - Results in Death), Ophthalmosis (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1d - n/a - Intra-muscular])	(EXELON (RIVASTIGMINE) (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), (MELATONIN (MELATONIN) (C - Sleep disorder - n/a - [n/a - n/a - Oral]), (AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - Hypertension - n/a - [n/a - n/a - Oral]), (BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - Hypertension - n/a - [n/a - n/a - Oral]), (COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE) (C - n/a - n/a - [n/a - n/a - Oral]), (ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM) (C - Gastrointestinal disorder prophylaxis - n/a - [n/a - n/a - Oral]), (ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE) (C - Hypertension - n/a - [n/a - n/a - Oral]), (MEMANTINE) (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), (MIRTAZAPINE) (C - Insomnia - n/a - [n/a - n/a - Oral]), (PARACETAMOL) (C - Pain - n/a - [n/a - n/a - Oral]), (RISPERIDONE) (C - Behaviour disorder - n/a - [n/a - n/a - Oral]), (WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP) (C - Atrial fibrillation - n/a - [n/a - n/a - Oral]), (COAPROLOL 150 MG/12.5 MG TABLETS) HYDROCHLOROTHIAZIDE, IRBESARTAN) (C - n/a - Dose not changed - [n/a - 1DF] - Oral), (MINISERAN HYDROCHLORIDE) (C - n/a - Dose not changed - [n/a - 30mg - Oral]), (NIBELIOL) (C - n/a - Dose not changed - [n/a - 1DF] - Oral), (OXAZEPAM) (C - n/a - Dose not changed - [n/a - 1DF] - Oral), (VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE) (C - n/a - Dose not changed - [n/a - 75mg - Oral]), (ZOPICLONE) (C - n/a - n/a - [n/a - 1DF] - Oral)	ICSR	
EU-EC-1000797860	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-1000797862	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular), KEPPRA 500 MG FILM-COATED TABLETS (LEVETIRACETAM) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (ACETYLSALICYLIC ACID, D,L-LYXINE ACETYLSALICYLATE) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (ATORVASTATIN, ATORVASTATIN CALCIUM) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (FUROSEMIDE) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (METFORMIN, METFORMIN HYDROCHLORIDE) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (OXAZEPAM) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80-90%) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral), (TURBRIE HYDROCHLORIDE) (S - Product used for unknown indication - Dose not changed - [n/a - 145ug - Oral]), (ZOPICLONE) (S - Product used for unknown indication - Dose not changed - [n/a - 1DF] - Oral)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000798227	11/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Asthenia (n/a - Fatal - Results in Death), Chills (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Makissie (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000798269	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000798261	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Asthenia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), General physical condition abnormal (24h - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intra-muscular])	Not reported	ICSR	
EU-EC-10007983472	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - n/a])	Not reported	ICSR	
EU-EC-10007983761	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - 3mL - n/a])	(LEVOCETIRIZINE DIHYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (OLMESARTAN MEDOXOMIL, ALOLOPINE, HYDROCHLOROTHIAZIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (ROSUVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]), (TITROPPIUM, TITROPPIUM BROMIDE, TITROPPIUM BROMIDE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10007985174	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthenia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intra-muscular)	(VALSARTAN, HYDROCHLOROTHIAZIDE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10007985236	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Lip oedema (n/a - Recovering/Resolving - Results in Death), Pyrexia (n/a - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intra-muscular])	(ALPRAZOLAM) (C - n/a - n/a - [n/a - 125mg - Oral]), (LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - 25ug - Oral])	ICSR	
EU-EC-10007985265	10/02/2021	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), Cerebral infarction (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovering/Resolving - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intra-muscular)	Not reported	ICSR	
EU-EC-10007986351	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1d - n/a - Intra-muscular])	(BUPRENORPHINE) (C - n/a - n/a - [n/a - n/a - n/a]), (OXYCODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (LIMSIAN (BIMOTROST) (C - n/a - n/a - [n/a - n/a - Oral]), (PILUA (DENDRAMB) (C - n/a - n/a - [n/a - n/a - n/a]), (BUPRENORPHINE) (C - n/a - n/a - [n/a - n/a - Transdermal]), (CARBOMER, CARBOMER 974F) (C - n/a - n/a - [n/a - n/a - Oral]), (FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL XINAFOATE) (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], (FUROSEMIDE) (C - n/a - n/a - [n/a - n/a - Oral]), (LACTULOSE) (C - n/a - n/a - [n/a - n/a - Oral]), (MACROGOL 4000) (C - n/a - n/a - [n/a - n/a - Oral]), (MEMANTINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - Oral]), (METOCLOPRAMIDE, METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - Oral]), (ONDANSETRON, ONDANSETRON HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - Oral]), (OXYCODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - Oral]), (OXYCODONE, OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE TRIHYDRATE) (C - n/a - n/a - [n/a - n/a - Intravenous (not otherwise specified)], (PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - Oral]), (POTASSIUM CHLORIDE) (C - n/a - n/a - [n/a - n/a - Oral]), (RAMPRI) (C - n/a - n/a - [n/a - n/a - Oral]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], (SBVASTATIN) (C - n/a - n/a - [n/a - n/a - Oral]), (THEOPHYLLINE, THEOPHYLLINE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - Oral]), (TITROPPIUM, TITROPPIUM BROMIDE, TITROPPIUM BROMIDE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], (WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP) (C - n/a - n/a - [n/a - n/a - Oral]), (ZOPICLONE) (C - n/a - n/a - [n/a - n/a - Oral])	Not reported	ICSR
EU-EC-10007973139	10/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10007973190	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Hypoharmlia (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Unknown)	NOT AVAILABLE (C - n/a - Unknown - ), (AMORCARENE HYDROCHLORIDE) (C - n/a - Unknown - ), (CANDESARTAN CILEXETIL) (C - n/a - Unknown - ), (CITICOLINE, CITICOLINE SODIUM) (C - n/a - Unknown - ), (FERROUS (II) GLYCINE SULFATE COMPLEX) (C - n/a - Unknown - ), (FUROSEMIDE) (C - n/a - Unknown - ), (IMEPRazole) (C - n/a - Unknown - ), (WARFARIN SODIUM) (C - n/a - Unknown - )	ICSR	
EU-EC-10007974146	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - Not applicable - [n/a - n/a - Intra-muscular])	(ALPRAZOLAM) (C - n/a - n/a - [n/a - 125mg - Oral]), (BICALUTAMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - n/a - n/a]), (DIGOXIN) (C - n/a - n/a - [n/a - n/a - n/a]), (FINASTERIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (ZOPICLONE) (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007974638	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intra-muscular])	(ELQUIS (APXIBAN) (C - n/a - n/a - [n/a - n/a - n/a]), (BICALUTAMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (CANDESARTAN CILEXETIL) (C - n/a - n/a - [n/a - n/a - n/a]), (DIGOXIN) (C - n/a - n/a - [n/a - n/a - n/a]), (FINASTERIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (ZOPICLONE) (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007975038	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	



EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group (as per reporter)	Patient Sex	Patient Age Group (as per reporter)	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-100751644	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death, Caused/Not Resolved - ), Ilex paralytic (via - Fatal - Results in Death, Caused/Not Resolved - ), Microcytic anaemia (via - Fatal - Results in Death, Caused/Not Resolved - ), Pneumonia (via - Fatal - Results in Death, Caused/Not Resolved - ), Asthma (via - Not Recovered/Not Resolved - ), Death (via - Fatal - Results in Death), Fargue (via - Not Recovered/Not Resolved - ), Hypotonia (via - Not Recovered/Not Resolved - )	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [1DF] - n/a)	XARELTO 15 MG (RIVAROXABAN) (C - Atrial fibrillation - n/a - [n/a - 1DF] - n/a), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - Constipation - n/a - [n/a - 1DF] - n/a)	ICSR
EU-EC-100757294	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular)	[ALENDRONATE SODIUM, ALENDRONIC ACID] (C - Osteoporosis - n/a - [n/a - 70mg - Oral]), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [n/a - Subconjunctival]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - Oral]), [EDNEPEZIL HYDROCHLORIDE] (C - Demens Alzheimer's type - n/a - [n/a - 5mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 500mg - Oral]), [VITAMIN D] (C - Osteoporosis - n/a - [n/a - 25ug - Oral])	ICSR
EU-EC-100757296	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100757330	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100757313	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100757326	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100757327	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular)	BETMIGRA (MIRABEGRON) (C - Hypertonic bladder - n/a - [n/a - 50mg - Oral]), XARELTO (RIVAROXABAN) (C - Thrombosis prophylaxis - n/a - [n/a - 15mg - Oral]), [BISACODYL] (C - Constipation - n/a - [n/a - 5mg - Oral]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - Oral]), [FLUORIDE, SODIUM FLUORIDE] (C - Dental disorder prophylaxis - n/a - [n/a - n/a - Dental]), [FUROSEMIDE] (C - Diuretic therapy - n/a - [n/a - 40mg - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Heart rate regular - n/a - [n/a - 50mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - Constipation - n/a - [n/a - 1DF] - Oral), [VITAMIN D, CALCIUM] (C - Mineral supplementation - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-100757331	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100757332	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100756781	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-100756833	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	COVID-19 (via - Unknown - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100756801	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	XARELTO (RIVAROXABAN) (C - n/a - n/a - [n/a - n/a])	ICSR
EU-EC-100756890	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100756916	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular]), COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	BUPRENORPHINE (BUPRENORPHINE) (C - n/a - n/a - [n/a - n/a - n/a]), MIDAZOLAM (MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOMETHAZOLE, CLOMETHAZOLE EDISILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCOPYRROLIUM BROMIDE, GLYCOPYRROLIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [METHANAMINE HIPURATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [EDROFOLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100756906	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	[LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1007561109	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Asthma (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death), Fall (via - Fatal - Results in Death, Other Medically Important Condition), Restlessness (via - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100754298	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100754364	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Apathy (via - Fatal - Results in Death, Life Threatening), Bradycardia (via - Fatal - Results in Death, Life Threatening), Bronchitis (via - Fatal - Results in Death, Life Threatening), Death (via - Fatal - Results in Death, Life Threatening), Fibrile infection (via - Fatal - Results in Death, Life Threatening), Rhinorrhea (via - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100754366	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death), Hypertensive crisis (via - Fatal - Results in Death), Pulmonary oedema (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100754365	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a), [NOT AVAILABLE] (S - Inev - Dose not changed - [n/a - 1000mg - n/a]), [NOT AVAILABLE] (S - Inev - Phosphoric acid increased - [n/a - 1DF] - n/a), [NOT AVAILABLE] (S - Patients care - Dose not changed - [n/a - 10mg - n/a]), COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	Not reported	ICSR
EU-EC-100754364	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - 10mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1DF] - n/a), NOT AVAILABLE (C - n/a - n/a - [n/a - 45mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 500mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 7.5mg - n/a]), [CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 1DF] - n/a), [CARBOMER] (C - n/a - n/a - [n/a - 1DF] - n/a), [THIAMINE HYDROCHLORIDE, DEVPANTHENOLOL, NICOTINAMIDE, BIOPFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1DF] - n/a)	ICSR
EU-EC-100754720	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cyanosis (via - Recovered/Resolved - ), Death (via - Fatal - Results in Death), Depressed level of consciousness (via - Recovered/Resolved - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	[EVENAFANINE, VENAFANINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [CASBARIA, Senna PASTE] (C - n/a - n/a - [n/a - n/a - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE, ANHYDROUS AMLODIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - ), [HALOPERIDOL, HALOPERIDOL BPF] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - ), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARAFFIN] (C - n/a - n/a - ), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - ), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - n/a - n/a]), [SOLFENAGIN SUCCINATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - ), [VENAFANINE, VENAFANINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE - GASTRO RESISTANT TABLET] (C - n/a - n/a - [n/a - n/a - n/a]), [ALCOLOINE, MALOOLINE BESLATE] (C - Hypertension - Not applicable - [n/a - n/a - n/a]), [PARACETAMOL, CAFFEINE, CODEINE PHOSPHATE] (C - Rheumatoid arthritis - Not applicable - [n/a - n/a - n/a]), [PREDNISOLONE] (C - Rheumatoid arthritis - Not applicable - [n/a - n/a - n/a])	ICSR
EU-EC-100754841	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Asthma (via - Unknown - ), Cerebral haemorrhage (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Fatigue (via - Unknown - ), Mabster (via - Unknown - ), Myalgia (via - Unknown - )	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ZINC] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100754966	07/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Pneumonia (via - Fatal - Results in Death)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	LANTUS (INSULIN GLARGINE) (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [STACIPTRIN] (STACIPTRIN) (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [FELODIPINE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Osteoarthritis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100752284	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Headache (via - Not Recovered/Not Resolved - Results in Death), Vomiting (via - Not Recovered/Not Resolved - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100752324	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1DF] - Intramuscular)	XARELTO (RIVAROXABAN) (C - Atrial fibrillation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100752454	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), General physical health deterioration (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-100752658	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac failure (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100752703	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Vaccination site pain (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100752756	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	[BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL, FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - 2DF] - n/a), [COLICALCIFEROL, CALCIUM, COLICALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1DF] - n/a), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 50mg - n/a]), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - 1DF] - n/a)	ICSR
EU-EC-100752941	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Asthma (via - Unknown - Caused/Not Resolved - ), Death (via - Fatal - Results in Death), Dizziness (via - Unknown - Caused/Not Resolved - ), Vomiting (via - Unknown - Caused/Not Resolved - )	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1007530163	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100753113	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	CELLEXIP (PICOXENOLATE MOFETIL) (C - Renal transplant - n/a - [n/a - 2g - n/a]), [CICLOSPORIN, CICLOSPORIN] (C - Renal transplant - n/a - [n/a - 75mg - n/a]), NOT AVAILABLE (C - Acute coarctation repair - n/a - [n/a - n/a - n/a]), [VALSARTAN, SACUBITRIL, VALSARTAN, SACUBITRIL] (C - Hypertension - n/a - [n/a - 5mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - 5mg - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE] (C - Renal transplant - n/a - [n/a - 2mg - n/a]), [TORASEMIDE] (C - Cardiac failure - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-1007534293	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1007515738	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1007515751	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1007515914	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ABILITY 10 MG TABLETS (ARRIPRAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYCHLOROQUINE SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [NICARDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1007516030	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU Local Number	EY Gateway Report Date	Report Type	Primary Source Qualification	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form		
EU-EC-1000715334	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular]]	Not reported	CSR	
EU-EC-1000715465	04/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - Intramuscular]]	Not reported	CSR	
EU-EC-1000715287	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Pneumonia (via - Fatal - Results in Death), Respiratory distress (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - Intramuscular]]	Not reported	CSR	
EU-EC-1000715620	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute myocardial infarction (MI - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - via - Not applicable - [via - 3mL - Intramuscular]]	[ACETYSALICYLIC ACID] (C - via - via - ), [DIHYDROXYALUMINUM SODIUM CARBONATE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - via - via - ), [HEBESULOL, NERIDROL, HYDROCHLORIDE] (C - via - via - ), [FENIBUDIPROL, FENIBUDIPROL ARGININE, FENIBUDIPROL, TERT-BUTYLAMINE] (C - via - via - ), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - via - via - ), [TRIMETAZOLONE DIIODIHYDROCHLORIDE] (C - via - via - )	CSR	
EU-EC-1000750294	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - via - via]]	Not reported	CSR	
EU-EC-1000750566	03/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anxiety (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Pneumonia (via - Unknown - Other Medically Important Condition), Respiratory distress (via - Unknown - Other Medically Important Condition)	TOZNAMERAN (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [1d - via - via]]	[LEVOTHYROXINE SODIUM] (C - via - via - [via - via - via]), [LORAZEPAM] (C - via - via - [via - via - via])	CSR	
EU-EC-1000750751	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Cardiac failure (3d - Fatal - Results in Death), Death (via - Fatal - Results in Death), Hypertension (3d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - via]]	Not reported	CSR	
EU-EC-1000748903	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Oxygen saturation decreased (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-1000748916	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-1000748927	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-1000749032	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 prophylaxis - via - [via - via - via]]	Not reported	CSR	
EU-EC-1000749033	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 prophylaxis - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007490796	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [1d - via - via - Intramuscular]]	[LISINAPRIL] (C - Hypertension - via - [via - 5mg - Oral]), [METANOLIC SODIUM] (C - Analgesic therapy, Anti-inflammatory therapy - via - [2d - 20mg] - Oral), [METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (C - via - via - [1d - 2x[4mg] - Oral]), [OXALIC ACID] (C - Analgesic therapy, Anti-inflammatory therapy - via - [via - 500mg] - Oral), [QUETIAPINE] (C - Agitation - via - [2d - 25mg] - Oral - More in CSR), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Antibiotic therapy - via - [via - 4mg] - Oral), [TAMBULOSIN HYDROCHLORIDE] (C - via - via - [via - 4mg] - Oral), [TRAMADOL HYDROCHLORIDE] (C - Analgesic therapy, Anti-inflammatory therapy - via - [1d - 200mg] - Oral - More in CSR)	CSR	
EU-EC-10007493759	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - 3mL - Intramuscular]]	[HYDROCHLOROTHIAZIDE] (C - via - via - [via - via - via])	CSR	
EU-EC-10007494159	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007494357	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Loss of consciousness (6d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007494983	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Fatigue (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - 3mL - Intramuscular]]	Not reported	CSR	
EU-EC-10007498969	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - Immunisation - via - [via - via - Intramuscular]]	[CLIMATEAZOLE, CLIMATEAZOLE (E)DISILATE] (C - via - via - [via - via - via]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - via - via - [via - via - via]), [ZOPICLONE] (C - via - via - [via - via - via]), [TRAIJENTA 5 MG FILM-COATED TABLETS (L)NAGLIPITIN] (C - via - via - [via - 5mg - via]), [BENBENAZIDE HYDROCHLORIDE, LEVODOPA, BENBENAZIDE, LEVODOPA] (C - via - via - [via - 1DF] - via), [BISOPROLOL FUMARATE] (C - via - via - [via - 2.5mg] - via), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - via - via - [via - via - via]), [CINCHOCANE HYDROCHLORIDE, PREDNISOLONE CAPROATE] (C - via - via - [via - via - via]), [COLECALCEROL, CALCIUM] (C - via - via - [via - 1DF] - via), [COLECALCEROL] (C - via - via - [via - via - via]), [CYANOCOBALAMIN] (C - via - via - [via - 1mg] - via), [FERRUS SULFATE] (C - via - via - [via - 100mg] - via), [FOLIC ACID] (C - via - via - [via - 1mg] - via), [FUROSEMIDE] (C - via - via - [via - 40mg] - via), [GLYCERYL TRINITRATE] (C - via - via - [via - via - via]), [LACTULOSE LACTULOSE LIQUID] (C - via - via - [via - via - via]), [MAGNESIUM CITRATE, MAGNESIUM LACTATE] (C - via - via - [via - 120mg] - via), [EMPRAZOLE] (C - via - via - [via - 20mg] - via), [PARACETAMOL] (C - via - via - [via - via - via]), [PROPYLENE GLYCOL] (C - via - via - [via - via - via]), [SALBUTAMOL] (C - via - via - [via - via - via]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - via - via - [via - via - via]), [TIOTROPOLIUM BROMIDE MONOHYDRATE] (C - via - via - [via - via - via])	CSR	
EU-EC-10007499124	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - Immunisation - via - [via - 3mL - Intramuscular]]	Not reported	CSR	
EU-EC-10007479399	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 prophylaxis - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007479649	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Abdominal pain (via - Unknown - ), Anal haemorrhage (via - Unknown - ), Back pain (via - Recovered/Resolved - ), Blood pressure decreased (via - Unknown - Other Medically Important Condition), C-reactive protein increased (via - Unknown - Other Medically Important Condition), Coma (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), General physical health deterioration (via - Unknown - Other Medically Important Condition), Heart rate decreased (via - Unknown - Other Medically Important Condition), Malaise (via - Unknown - ), Oxygen saturation decreased (via - Recovered/Resolved - Other Medically Important Condition), Somnolence (via - Unknown - Other Medically Important Condition), Tachypnea (via - Unknown - Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular]]	[ACETYSALICYLIC ACID] (C - via - via - [via - 100mg] - Oral), [HYDROXYCARBAMIDE] (C - Myelodysplastic neoplasm - via - [via - 1000mg] - Oral), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - via - via - [via - 5mg] - Oral), [TORASEMIDE SODIUM] (C - via - via - [via - 100mg] - Oral)	CSR	
EU-EC-10007480165	01/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), General physical condition deteriorated (22d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007480253	01/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - Immunisation - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007482017	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Fatigue (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - via - via - [1d - via - Intramuscular]]	[COLECALCEROL, CALCIUM, COLECALCEROL, CALCIUM CARBONATE] (C - Supplementation therapy - via - [via - via - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Dementia Alzheimer's type - via - [via - via - Oral])	CSR	
EU-EC-10007486506	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - 3mL - Intramuscular]]	[OXAZEPAM] (C - Relaxation therapy, Sleep disorder - via - [via - via - Oral]), [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - via - via - [via - via - via]), [NATIFUNGIN, NITROGEN, DIMETICONE, DIMETICONE, COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS SILICA, COLLOIDAL ANHYDROUS DIMETICONE 100%] (C - via - via - [via - via - via]), [EPINEPHRINE BITARTRATE, LIDOCAINE HYDROCHLORIDE, LIDOCAINE, LIDOCAINE HYDROCHLORIDE] (C - via - via - [via - via - via]), [FLUTICASON PROPRIONATE, FORMOTEROL FUMARATE DIHYDRATE, FLUTICASON PROPRIONATE, FORMOTEROL FUMARATE DIHYDRATE PLEUR.] (C - via - via - [via - via - via]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - via - via - [via - via - via]), [GLYCEROL] (C - via - via - [via - via - via]), [GLYCOPYRROLIUM BROMIDE, GLYCOPYRROLIUM BROMIDE, NESTOXIME METHYLSULFATE] (C - via - via - [via - via - via]), [HALOPERIDOL, HALOPERIDOL, DECANATE] (C - via - via - [via - via - via]), [MOMETASON FURATE] (C - via - via - [via - via - via]), [MORPHINE HYDROCHLORIDE] (C - via - via - [via - via - via]), [OXAZEPAM] (C - via - via - [via - via - via]), [PARACETAMOL] (C - via - via - [via - via - via]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - via - via - [via - via - via]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - via - via - [via - via - via])	Not reported	CSR
EU-EC-10007486558	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Fatigue (via - Fatal - Results in Death), Hypertensive emergency (via - Recovered/Resolved - Other Medically Important Condition), Pain (1d - Unknown - Other Medically Important Condition), Rales (1d - Unknown - )	COMIRNATY (TOZNAMERAN) [S - via - via - [1DF] - via]]	Not reported	CSR	
EU-EC-10007487006	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Somnolence (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Productive cough (via - Fatal - Results in Death), Wheezing (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - 3mL - Intramuscular]]	[ACOPY (BRANZOLAMIDE)] (C - via - via - [via - via - via]), [ACETYSALICYLIC ACID] (C - via - via - [via - 75mg] - via), [CITALOPRAM] (C - via - via - [via - 10mg] - via), [CYANOCOBALAMIN] (C - via - via - [via - 1mg] - via), [FENTANYL, FENTANYL CITRATE] (C - via - via - [via - via - via]), [FOLIC ACID] (C - via - via - [via - 1mg] - via), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - via - via - [via - via - via]), [GABAPENTIN] (C - via - via - [via - 100mg] - via), [LATANOPROST] (C - via - via - [via - via - via]), [METOPROLOL, METOPROLOL TARTRATE] (C - via - via - [via - 50mg] - via), [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - via - via - [via - via - via]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - via - via - [via - via - via]), [OXALIC ACID] (C - via - via - [via - via - via]), [UREA] (C - via - via - [via - via - via])	CSR	
EU-EC-10007477398	31/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - Immunisation - via - [via - via - Intramuscular]]	Not reported	CSR	
EU-EC-1000747306	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Drug withdrawn - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-1000747313	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-1000747406	30/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (25d - Fatal - Results in Death), Pneumonia (25d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [25d - via - Intramuscular]]	Not reported	CSR	
EU-EC-10007474065	30/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (5d - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death), Influenza like illness (5d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - Intramuscular]]	Not reported	CSR	
EU-EC-10007481795	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-10007481911	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-10007481994	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular]]	Not reported	CSR	
EU-EC-10007483064	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - Immunisation - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007483995	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	No	Body temperature increased (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Malaise (via - Fatal - Results in Death), Tumor (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - Intramuscular]]	Not reported	CSR	
EU-EC-10007485137	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - Intramuscular]]	Not reported	CSR	
EU-EC-10007485196	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - via - via]]	Not reported	CSR	
EU-EC-10007487137	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) [S - COVID-19 immunisation - via - [via - 3mL - Intramuscular]]	[METOCLOPRAMIDE (METOCLOPRAMIDE)] (C - via - via - [via - via - via]), [PROLIA (DENOSUMAB)] (C - via - via - [via - via - via]), [RESOLOR (PRUCALOPRIDE)] (C - via - via - [via - via - via]), [BENBENAZIDE HYDROCHLORIDE, LEVODOPA, BENBENAZIDE, LEVODOPA] (C - via - via - [via - via - via]), [BUPRENORPHINE] (C - via - via - [via - via - via]), [CARBIDOPA, LEVODOPA] (C - via - via - [via - via - via]), [CLOZAPINE] (C - via - via - [via - via - via]), [COLECALCEROL] (C - via - via - [via - via - via]), [CYANOCOBALAMIN] (C - via - via - [via - via - via]), [DUCOSATE SODIUM, SORBITOL, (E403)] (C - via - via - [via - via - via]), [ECONAZOLE, ECONAZOLE NITRATE, ECONAZOLE NITRATE, ZINC OXIDE] (C - via - via - [via - via - via]), [FOLIC ACID] (C - via - via - [via - via - via]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - via - via - [via - via - via]), [LACTULOSE] (C - via - via - [via - via - via]), [MORPHINE HYDROCHLORIDE] (C - via - via - [via - via - via]), [OXAZEPAM] (C - via - via - [via - via - via]), [PARACETAMOL] (C - via - via - [via - via - via]), [POTASSIUM CHLORIDE] (C - via - via - [via - via - via]), [PROPYLENE GLYCOL] (C - via - via - [via - via - via]), [SODIUM PICOSULFATE] (C - via - via - [via - via - via]), [CHLORHEXIDINE] (C - via - via - [via - via - via])	CSR	

EU Local Number	EV Gateway Report Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group (as reported)	Patient Sex	Patient Age Group (as reported)	Patient Sex	Parent/Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
			Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	No	Death (via - Fatal - Results in Death)		[CITALOPRAM] (C - via - via - [via - 10mg - via]), [LACTULOSE, LACTULOSE LIQUID] (C - via - via - [via - 20mL - via]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - via - via - [via - 60ug - via]), [MEMANTINE HYDROCHLORIDE] (C - via - via - [via - 20mg - via]), [OXAZEPAM] (C - via - via - [via - via - via]), [RISPERIDONE] (C - via - via - [via - 25mg - via]), [SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIHYDRATE] (C - via - via - [via - via - Recall]), [SODIUM FLUORIDE] (C - via - via - [via - via - via]), [TIMOLOL, PLOCAFINE HYDROCHLORIDE] (C - via - via - [via - via - Ophthalmic]), [TIMOLOL] (C - via - via - [via - via - via])		
EU-EC-1000747070	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular])		Not reported	CSR
EU-EC-1000747140	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - 1[DF] - via])		Not reported	CSR
EU-EC-10007451396	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - 1[DF] - Intramuscular])		Not reported	CSR
EU-EC-10007452251	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - via - via - [via - via - via])		Not reported	CSR
EU-EC-10007462952	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - 3mL - Intramuscular])		Not reported	CSR
EU-EC-10007465951	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZNAMERAN) (S - Prophylaxis - via - [via - via - Unknown])		Not reported	CSR
EU-EC-10007469877	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		[FIAP (INSULIN ASPART)] (C - via - via - [via - via - via]), TRESBA (INSULIN DEGLUQUE) (C - via - via - [via - via - via]), [ATENLOL, ATENLOL BP] (C - via - via - [via - via - via]), [DONEPEZIL] (C - via - via - [via - via - via]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - via - via - [via - via - via]), [LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE] (C - via - via - [via - via - via]), [PARACETAMOL] (C - via - via - [via - via - via]), [THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - via - via - [via - via - via])	
EU-EC-10007440863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 1[DF] - Intramuscular])		Not reported	CSR
EU-EC-10007440966	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 1[DF] - Intramuscular])		[AMODARONE HYDROCHLORIDE] (C - via - via - [via - 200mg - Oral]), [BISOPROLOL, FLUMARATE] (C - via - via - [via - 1.25mg - Oral]), [FLUDIONIDE] (C - via - via - [via - via - Oral]), [FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL XINAFOATE] (C - via - via - [via - via - Respiratory (inhalation)]), [FUROSEMIDE] (C - via - via - [via - 40mg - Oral]), [LATANOPROST] (C - via - via - [via - via - Ophthalmic]), [MORPHINE SULFATE] (C - via - via - [via - via - Oral]), [OXAZEPAM] (C - via - via - [via - via - Oral])	
EU-EC-10007441212	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), Increased bronchial secretion (via - Fatal - Results in Death), Pneumonia (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular]), [FENTANYL] (S - Pain - Dose not changed - [via - 0.2mg - Transdermal])		[LUPAZOLAM] (C - via - via - [via - via - via]), [COLCALSIFEROL] (C - via - via - [via - via - via]), [ESTERCUA, STERCUA GUM, STERCUA URENS ROXB. GUM] (C - via - via - [via - via - Recall])	
EU-EC-10007444663	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZNAMERAN) (S - via - via - [via - 1[DF] - via])		[LUMANA (EDOXABAN, EDOXABAN TOsylATE)] (C - via - via - [via - via - Recall]), [COLECALCIFEROL] (C - via - via - [via - via - via]), [FOLIC ACID] (C - via - via - [via - via - via]), [FUROSEMIDE] (C - via - via - [via - 20mg - via]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - via - via - [via - via - via]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - via - via - [via - via - 10mg - via])	
EU-EC-10007444664	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death, Life Threatening), Fatigue (via - Fatal - Results in Death, Life Threatening), Serum sickness (via - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZNAMERAN) (S - via - via - [via - 1[DF] - via])		[CLOPIDDOL] (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - via - via - [via - via - 75mg - via]), [LORAZEPAM] (C - via - via - [via - via - [via - 2.5mg - via]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - via - via - [via - via - via]), [CANDESARTAN CILEXETIL] (C - via - via - [via - via - 8mg - via]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - via - via - [via - via - 12.5mg - via])	
EU-EC-10007444951	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 3mL - Intramuscular])		[FENTANYL, FENTANYL, FENTANYL CITRATE] (C - via - via - [via - via - Unknown]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - via - via - [via - via - Unknown]), [ACETYSALICYLIC ACID] (C - via - via - [via - via - Unknown]), [CALCIUM CITRATE, MAIZE STARCH, STEARIC ACID, TALC, CALCIUM CITRATE] (C - via - via - [via - via - Unknown]), [COLECALCIFEROL] (C - via - via - [via - via - Unknown]), [ENOXAPARIN SODIUM] (C - via - via - [via - via - Unknown]), [FOLIC ACID, DRIES FERROUS SULFATE] (C - via - via - [via - via - via - Unknown]), [FUROSEMIDE] (C - via - via - [via - via - Unknown]), [ROSIGLIXITATIN, CALCIUM] (C - via - via - [via - via - Unknown]), [SPIRONOLACTONE] (C - via - via - [via - via - Unknown])	
EU-EC-10007445203	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - via - via - [via - via - via])		Not reported	CSR
EU-EC-10007445211	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - via - via - [via - 3mL - Subcutaneous])		Not reported	CSR
EU-EC-10007445410	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death), General physical condition abnormal (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		Not reported	CSR
EU-EC-10007446819	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death), General physical health deterioration (via - Recovered/Resolved -)	COMIRNATY (TOZNAMERAN) (S - Immunisation - via - [via - via - Intramuscular])		Not reported	CSR
EU-EC-10007446863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - 3mL - Intramuscular])		[ATORVASTATIN] (C - via - via - [via - via - via]), [BISOPROLOL, BISOPROLOL, FLUMARATE, BISOPROLOL, HEMIFUMARATE] (C - via - via - [via - via - via]), [HYDROCHLOROTHIAZIDE] (C - via - via - [via - via - via]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - via - via - [via - via - via]), [OXAZEPAM] (C - via - via - [via - via - via]), [RAMIPRIL] (C - via - via - [via - via - via]), [WARFARIN SODIUM] (C - via - via - [via - via - via])	
EU-EC-10007446873	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - via - via - [via - via - via])		Not reported	CSR
EU-EC-10007446887	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death), Fatigue (via - Fatal - Results in Death), Productive cough (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - Immunisation - via - [via - via - via])		[ACETYSALICYLIC ACID] (C - via - via - [via - via - via]), [METFORMIN] (C - via - via - [via - via - via]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - via - via - [via - via - via]), [PARACETAMOL] (C - via - via - [via - via - via]), [ANALVA 100 MG FILM-COATED TABLETS (SITAGLIPTIN)] (C - via - via - [via - via - Oral]), [MMPARA 30 MG FILM-COATED TABLETS (ONACALCET, CINACALCET HYDROCHLORIDE)] (C - via - via - [via - via - 30mg - Oral]), [AMOXICILIN SODIUM, CLAVULANIC ACID, AMOXICILIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILIN, POTASSIUM CLAVULANATE] (C - via - via - [via - via - 1g - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - via - via - [via - via - 20mg - Oral]), [BISOPROLOL, FLUMARATE, BISOPROLOL, HEMIFUMARATE] (C - via - via - [via - via - 5mg - Oral]), [DEXAMETHASONE SODIUM PHOSPHATE] (C - via - via - [via - 6mg - Oral]), [SODIUM PHOSPHATE, ANHYDROUS, CALCIUM MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, DISODIUM PHOSPHATE, ANHYDROUS, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BISDIHYDROGENPHOSPHATE MONOHYDRATE, DISODIUM PHOSPHATE, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BISDIHYDROGENPHOSPHATE MONOHYDRATE] (C - via - via - [via - via - 10[mg] - Oral]), [ENALAPRIL, ENALAPRIL MALEATE] (C - via - via - [via - 5mg - Oral]), [OXAZEPAM] (C - via - via - [via - 10mg - Oral]), [PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - via - via - [via - via - Oral]), [TRIZAPARIN, TINZAPARIN SODIUM] (C - Anal inhalation - via - [via - 7mL - Subcutaneous])	
EU-EC-10007431167	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 1[DF] - Intramuscular])		Not reported	CSR
EU-EC-10007431177	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 1[DF] - Intramuscular])		Not reported	CSR
EU-EC-10007431178	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), Pneumonia (via - Not Recovered/Not Resolved - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 1[DF] - Intramuscular])		Not reported	CSR
EU-EC-10007431613	25/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	COVID-19 (via - Not Recovered/Not Resolved - Caused Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused Prolonged Hospitalisation), Drug ineffective (via - Not Recovered/Not Resolved - Caused Prolonged Hospitalisation), Dyspnoea (via - Unknown - Caused Prolonged Hospitalisation), Malaise (via - Unknown - Caused Prolonged Hospitalisation), Vomiting (via - Unknown - Caused Prolonged Hospitalisation)	TOZNAMERAN (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - via - via])		[RIVASTIGMINE (RIVASTIGMINE, RIVASTIGMINE HYDROGEN TARTRATE)] (C - Parkinson's disease - via - [via - via - via])	
EU-EC-10007433053	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), Warming (via - Unknown - Caused Prolonged Hospitalisation), Blood pressure immeasurable (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Nausea (via - Fatal - Results in Death), Personality change (via - Fatal - Results in Death), Renal failure (via - Fatal - Results in Death), Unresponsive to stimuli (via - Fatal - Results in Death), Vomiting (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - via])		Not reported	CSR
EU-EC-10007433980	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), General physical health deterioration (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		[DORZOLAMIDE, TIMOLOL] (C - via - via - [via - via - via]), [LATANOPROST] (C - via - via - [via - via - via]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - via - via - [via - 25ug - via]), [PARACETAMOL] (C - via - via - [via - 1000mg - via]), [SODIUM FLUCIDILATE] (C - via - via - [via - via - via]), [UREA] (C - via - via - [via - via - via])	
EU-EC-10007436275	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - via - via])		Not reported	CSR
EU-EC-10007422470	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Agitation (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [via - 1[DF] - via])		Not reported	CSR
EU-EC-10007432315	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Cardiac arrest (via - Fatal - Results in Death), Circulatory collapse (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - via])		Not reported	CSR
EU-EC-10007432313	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - via])		Not reported	CSR
EU-EC-10007423721	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])		Not reported	CSR
EU-EC-10007423626	25/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (16d - Fatal - Results in Death), Death (16d - Fatal - Results in Death), General physical condition abnormal (16d - Fatal - Results in Death), Pain (16d - Fatal - Results in Death), Respiratory distress (16d - Fatal - Results in Death), Unresponsive to stimuli (16d - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - via])		Not reported	CSR
EU-EC-10007427048	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - via - via - [via - 1[DF] - via])		[ADENURIC 80 MG FILM-COATED TABLETS (FEBUXOSTAT)] (C - via - via - [via - 1[DF] - via]), NOT AVAILABLE (C - via - via - [via - 1[DF] - via]), NOVORIN (S) (INSULIN ASPART, INSULIN ASPART, INSULIN ASPART PROTAMINE) (C - via - via - [via - via - via]), [MELCICLINE, MELCICLINE MESILATE] (C - via - via - [via - via - 50[mg] - via]), [BETAMETHASONE DIPROPIONATE, GENTAMICIN, BETAMETHASONE DIPROPIONATE, GENTAMICIN SULFATE, GENTAMICIN SULFATE, BETAMETHASONE (PH. EUR.), GENTAMICIN, BETAMETHASONE] (C - via - via - [via - via - via]), [CETIRIZINE DIHYDROCHLORIDE] (C - via - via - [via - 10[DF] - via]), [DILTIAZEM] (C - via - via - [via - 10[DF] - via]), [D-LIMONENE] (C - via - via - [via - via - via]), [HYDROCHLOROTHIAZIDE, CANDESARTAN CILEXETIL] (C - via - via - [via - 10[DF] - via]), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - via - via - [via - 10[DF] - via]), [HYPPROLOSE] (C - via - via - [via - 10[mg] - via]), [LIQUID PARAFFIN] (C - via - via - [via - via - via]), [MELALEUCA ALTERNIFOLIA OIL] (C - via - via - [via - via - via]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISUCCINATE] (C - Ezema - via - [via - 5[DF] - via]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - via - via - [via - 1[DF] - via]), [SOYA BEAN OIL, REFINED PHYEUR., SOYA OIL, SOYA-BEAN OIL, REFINED] (C - via - via - [via - via - via]), [VASSILINE] (C - via - via - [via - via - via])	
EU-EC-10007433008	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), No adverse event (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		Not reported	CSR
EU-EC-10007433048	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (via - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		Not reported	CSR
EU-EC-10007433130	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		Not reported	CSR
EU-EC-10007433462	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		Not reported	CSR
EU-EC-10007433602	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (via - Fatal - Results in Death), Fatigue (via - Unknown -), Malaise (via - Unknown -)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - via - via])		Not reported	CSR
EU-EC-10007433754	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not	No	No	Death (via - Fatal - Results in Death)	COMIRNATY (TOZNAMERAN) (S - COVID-19 immunisation - via - [via - via - Intramuscular])		Not reported	CSR

EU Local Number	EV Gateway Report Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Reference	Literature Reference Available	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
			Professional	European Economic Area	Not available	More than 18 Years	Not Specified	Female	No	Decreased appetite (04 - Fatal - Results in Death), Diet refusal (04 - Fatal - Results in Death)			
EU-EC-1000740423	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 18 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - 1]DF - Intramuscular)	Not reported	CSR
EU-EC-1000740420	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [v/a - 1]DF - Intramuscular)	Not reported	CSR
EU-EC-1000740454	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 18 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - 1]DF - Intramuscular)	Not reported	CSR
EU-EC-1000741019	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - 1]DF - Intramuscular)	Not reported	CSR
EU-EC-1000741429	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [v/a - n/a - n/a])	Not reported	CSR
EU-EC-1000741430	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 18 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Resuscitation (v/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000741431	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (v/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000738046	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Adiposis (v/a - Not Recovered/Not Resolved - ), Blood lactic acid increased (v/a - Not Recovered/Not Resolved - ), Confusional state (v/a - Not Recovered/Not Resolved - ), Death (v/a - Fatal - Results in Death), Electrocardiogram ST segment elevation (v/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hemiparesis (v/a - Not Recovered/Not Resolved - Other Medically Important Condition), Right ventricular enlargement (v/a - Not Recovered/Not Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-1000738958	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000734218	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000737506	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [v/a - n/a - n/a])	Not reported	CSR
EU-EC-1000737624	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000737616	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Hypotension (v/a - Fatal - Results in Death), Livedo reticularis (v/a - Fatal - Results in Death), Loss of consciousness (v/a - Fatal - Results in Death), Peripheral coldness (v/a - Fatal - Results in Death), Respiratory rate increased (v/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	BUMETANIDE [BUMETANIDE] (C - n/a - n/a - [v/a - n/a - n/a]), MELATONIN [MELATONIN] (C - n/a - n/a - [v/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [v/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [v/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [v/a - n/a - n/a]), [CASSIA] (C - n/a - n/a - [v/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [v/a - n/a - n/a]), [DMETICONE] (C - n/a - n/a - [v/a - n/a - n/a]), [DOCUSATE SODIUM] (C - n/a - n/a - [v/a - n/a - n/a]), [DOXYCYCLINE HYCLATE] (C - n/a - n/a - [v/a - n/a - n/a]), [SISOSORBIDE MONONITRATE] (C - n/a - n/a - [v/a - n/a - n/a]), [MACROGOL 3350] (C - n/a - n/a - [v/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [v/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [v/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [v/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [v/a - n/a - n/a]), [TRACETIN] (C - n/a - n/a - [v/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [v/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [v/a - 20mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [v/a - 75ug - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [v/a - 100mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [v/a - 5mg - n/a]), [RAMPRI] (C - n/a - n/a - [v/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [v/a - n/a - n/a])	CSR
EU-EC-1000736976	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000736468	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000736730	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [v/a - 30ug - Intramuscular])	AERUS 5 MG FILM-COATED TABLET [DESLORATADINE] (C - n/a - n/a - [v/a - 5mg - n/a]), ARANESP 30 MICROGRAMS SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE [BARBIPECETIN ALFA] (C - n/a - n/a - [v/a - 1DF] - n/a), [ACETYLCHOLINE] (C - n/a - n/a - [v/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [v/a - 100mg - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [v/a - n/a - n/a]), [CARBAMER] (C - n/a - n/a - [v/a - n/a - n/a]), [DALTEPARIN SODIUM] (C - n/a - n/a - [v/a - 1DF] - n/a), [FINASTERIDE] (C - n/a - n/a - [v/a - 5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [v/a - 200mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [v/a - n/a - n/a]), [GLYCEROL] (C - n/a - n/a - [v/a - n/a - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION 10%] (C - n/a - n/a - [v/a - n/a - n/a]), [GLYCOPYRROLONIUM BROMIDE] (C - n/a - n/a - [v/a - 1mL - n/a]), [HALOPERIDOL] (C - n/a - n/a - [v/a - n/a - n/a]), [HYPERMILLORE] (C - n/a - n/a - [v/a - n/a - n/a]), [LATHAPROST] (C - n/a - n/a - [v/a - n/a - n/a]), [MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [v/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [v/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [v/a - 10mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [v/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [v/a - 1000mg - n/a]), [POTASSIUM SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [v/a - n/a - n/a]), [SODIUM PHOSPHATE, SODIUM PHOSPHATE] (C - n/a - n/a - [v/a - n/a - n/a]), [SODIUM POLYSTYRENE SULFONATE] (C - n/a - n/a - [v/a - n/a - n/a])	CSR
EU-EC-1000736290	17/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death), General physical health deterioration (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000735746	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac fibrillation (v/a - Unknown - Results in Death), Death (v/a - Fatal - Results in Death), Makiss (v/a - Unknown - Results in Death), Syncope (v/a - Unknown - Results in Death), Vomiting (v/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [v/a - n/a - n/a])	Not reported	CSR
EU-EC-10007381020	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - 1]DF - Intramuscular)	Not reported	CSR
EU-EC-1000734524	14/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death), Pneumonia (v/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-1000734093	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - n/a - n/a])	Not reported	CSR
EU-EC-1000734742	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - 1]DF - Intramuscular)	ELIGUS [APIXABAN] (C - Thrombosis prophylaxis - n/a - [v/a - 5mg - Oral]), [ATORVASTATIN] (C - Cardiovascular event prophylaxis - n/a - [v/a - 80mg - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [v/a - 10mg - Oral]), [METOPROLOL SUCCONATE, METOPROLOL TARTRATE] (C - Heart rate regular - n/a - [v/a - 25mg - Oral]), [RISPERIDONE] (C - Aggression - n/a - [v/a - 25mg - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [v/a - 50mg - Oral]), [TAMBOLOSIN HYDROCHLORIDE] (C - Dysuria - n/a - [v/a - 4mg - Oral])	CSR
EU-EC-1000733363	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000733536	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute myocardial infarction (v/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (v/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (v/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [v/a - n/a - n/a])	Not reported	CSR
EU-EC-1000733936	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death), Resuscitation (v/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR
EU-EC-1000731864	08/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death), Mabiose (v/a - Fatal - Results in Death), Vomiting (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [v/a - n/a - Intramuscular])	[CARVEDILOL] (C - n/a - n/a - [v/a - 25mg - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [v/a - 20mg - n/a]), [COLECALCIFEROL, CALCIUM COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [v/a - 1DF] - n/a), [FUROSEMIDE] (C - n/a - n/a - [v/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [v/a - 100ug - n/a]), [PARACETAMOL] (C - n/a - n/a - [v/a - 1000mg - n/a]), [UREA] (C - n/a - n/a - [v/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [v/a - n/a - n/a])	CSR
EU-EC-1000731351	07/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death), Renal failure (v/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [v/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	Not Specified	Female	No	Condition aggravated (v/a - Fatal - Results in Death, Life Threatening), Death (v/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - n/a - n/a])	BETMIG (MIRABEGRON) (C - n/a - Not applicable - [v/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [v/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - n/a - Not applicable - [v/a - n/a - n/a]), [CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE] (C - n/a - Not applicable - [v/a - n/a - n/a]), [COLECALCIFEROL, CYANOCOBALAMIN, ERGOCALCIFEROL, RETINOL ACETATE, ERGOCALCIFEROL, TOCOPHERYL ACETATE] (C - n/a - Unknown - ), [CYANOCOBALAMIN] (C - n/a - Not applicable - [v/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - Not applicable - [v/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Not applicable - [v/a - n/a - n/a]), [ESTRADIOL, ESTRADIOL HEMHYDRATE] (C - n/a - Not applicable - ), [GOLIC ACID] (C - n/a - Not applicable - [v/a - n/a - n/a]), [LACTOBACILLUS ACIDOPHILUS, 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 - [v/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - Not applicable - [v/a - n/a - n/a]), [RISPERIDONE] (C - n/a - Not applicable - [v/a - n/a - n/a]), [VITAMIN D] (C - n/a - Not applicable - )	CSR
EU-EC-1000730529	06/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [v/a - n/a - n/a])	Not reported	CSR
EU-EC-1000728416	05/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (v/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000728198	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (04 - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000728206	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (v/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (v/a - Unknown - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [v/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1000728310	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (v/a - Fatal - Results in Death, Life Threatening), Death (v/a - Fatal - Results in Death, Life Threatening), Pulmonary embolism (v/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [v/a - 3mL - Intramuscular])	Not reported	CSR