

Line Listing Report
Time run: 05/07/2021 18:32:59

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age (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])	ICSR Form
EU-EC-10009235290	02/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abortion threatened (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009237568	02/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved -), Pregnancy after post coital contraception (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Transient ischaemic attack - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009239407	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Diarhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Neonatal disorder (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting projectile (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009242373	02/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Haematoma (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Unknown -), Placenta praevia haemorrhage (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (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])	ICSR
EU-EC-10009243256	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009243552	02/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Uterine contractions abnormal (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009221126	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Ascites (n/a - Unknown - Congenital Anomaly), Foetal hypokinesia (n/a - Unknown - Congenital Anomaly), Hydrops foetalis (n/a - Unknown - Congenital Anomaly), Maternal exposure during pregnancy (n/a - Unknown - Congenital Anomaly), Oedema (n/a - Unknown - Congenital Anomaly), Pleural effusion (n/a - Unknown - Congenital Anomaly), Trisomy 21 (n/a - Unknown - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009228715	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009227675	01/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (4d - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10009230399	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental]), [LANSOPRAZOLE] (C - Gastritis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009230658	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal death (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009231644	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dry mouth (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Euphoric mood (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eyelid disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Glassy eyes (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Morning sickness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mydriasis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000923241	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Contusion (n/a - Recovering/Resolving - Life Threatening, Disabling, Other Medically Important Condition), Epistaxis (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Hallucination (n/a - Recovering/Resolving - Life Threatening, Disabling, Other Medically Important Condition), Migraine (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009232393	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Male	Yes	Foetal heart rate decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Foetal hypokinesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10009233416	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009205878	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009209962	30/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion induced (n/a - Unknown - Other Medically Important Condition), Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000921058	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Stillbirth (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009211971	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10009211974	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (14d - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009213103	30/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Foetal death (n/a - Fatal - Results in Death), Generalised oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Transplacental])	Not reported	ICSR
EU-EC-10009214294	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (15d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Disabling), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009214303	30/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009214372	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	High foetal head (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoesthesia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal discomfort (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pelvic pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sciatica (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[IBUPROFEN, IBUPROFEN LYSINE, IBUPROFEN PH. EUR., IBUPROFEN SODIUM, IBUPROFEN SODIUM DIHYDRATE] (C - Chest pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009215015	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CODEINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009216129	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition), Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009216144	30/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Dysmenorrhoea (12d - Recovered/Resolved - Other Medically Important Condition), Heavy menstrual bleeding (5d - Recovered/Resolved - Other Medically Important Condition), Polycystic ovaries (n/a - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (n/a - Recovered/Resolved - Other Medically Important Condition), Umbilical cord abnormality (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CYPROTERONE ACETATE] (C - Alopecia - n/a - [n/a - 100mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Polycystic ovaries - n/a - [n/a - 300mg - n/a]), [SPIRONOLACTONE] (C - Alopecia - n/a - [n/a - 100mg - n/a]), [THYROXINE] (C - n/a - n/a - [n/a - 125mg - n/a])	ICSR
EU-EC-10009216935	30/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure before pregnancy (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009219615	30/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Exposure during pregnancy (n/a - Unknown -), Stillbirth (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[EMPAGLIFLOZIN [EMPAGLIFLOZIN]] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009184719	29/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Premature delivery (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009185137	29/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion early (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009188417	29/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (0d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [ALENDRONIC ACID, COLECALCIFEROL] (C - n/a - Unknown - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10009188589	29/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Fatigue (2d - Recovered/Resolved - Congenital Anomaly), Limb injury (n/a - Recovered/Resolved - Congenital Anomaly), Peripheral swelling (3d - Recovered/Resolved - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009188940	29/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009190646	29/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (1d - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10009191373	29/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (6d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009192979	29/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Foetal death (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	[BIOFLAVONOIDS, MICRONISED PURIFIED FLAVONOIC FRACTION] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009193354	29/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Nausea (1h - Recovered/Resolved -), Uterine hypertonus (4h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1(Df) - Intramuscular])	[ASCORBIC ACID, FERROUS SULFATE] (C - Anaemia - n/a - [n/a - 1(Df) - Oral]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - 10mg - Oral])	ICSR
EU-EC-10009198060	29/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during breast feeding (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved -), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009203786	29/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009204607	29/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Fatal - Results in Death, Other Medically Important Condition), Heavy menstrual bleeding (n/a - Unknown - Results in Death, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Results in Death, Other Medically Important Condition), Menstruation irregular (n/a - Unknown - Results in Death, Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009186878	28/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (7d - Recovered/Resolved - Congenital Anomaly, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Mood altered (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Pregnancy, Vitamin supplementation - n/a - [n/a - 5mg - n/a - More in ICSR]), [VITAMINS NOS] (C - Pregnancy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009189767	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Face presentation (4d - Recovered/Resolved - Disabling), Oedema (4d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009189860	28/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Abortion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[TURMERIC] (C - Nutritional supplementation - n/a - [n/a - 3(Df) - n/a])	ICSR
EU-EC-10009170211	28/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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
			Healthcare Professional	European Economic Area	available	Years	Specified				applicable - [1d - n/a - n/a]		
EU-EC-10009170216	28/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Decidual cast (n/a - Recovering/Resolved - Other Medically Important Condition), Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009170287	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Abortion spontaneous (5d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009171512	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Headache (2d - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -), Uterine contractions during pregnancy (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009175217	28/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Foetal death (n/a - Fatal - Results in Death, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Unknown -), Foetal growth restriction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Transplacental])	ICSR
EU-EC-10009177659	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Anembryonic gestation (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1(Df) - Intramuscular]), ESOMEPRAZOLE [ESOMEPRAZOLE] (S - Product used for unknown indication - n/a - [n/a - n/a - Oral])	Not reported	ICSR
EU-EC-10009143535	25/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009144638	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10009144859	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Gestational diabetes (n/a - Unknown - Other Medically Important Condition), Hypothyroidism (n/a - Unknown - Other Medically Important Condition), Maternal exposure timing unspecified (n/a - Unknown -), Type 1 diabetes mellitus (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009145547	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - Other Medically Important Condition), Foetal death (n/a - Unknown - Other Medically Important Condition), Gestational diabetes (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [OMEPRAZOLE] (C - Oesophagitis - n/a - [16d - 20mg - n/a - More in ICSR]), [VITAMINS NOS] (C - Pregnancy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009145659	25/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abdominal pain (25d - Recovered/Resolved -), Abortion spontaneous (0d - Recovered/Resolved - Other Medically Important Condition), Asthenia (2d - Recovered/Resolved -), Fatigue (14d - Recovered/Resolved -), Foetal death (0d - Recovered/Resolved - Other Medically Important Condition), Hyperaesthesia (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Progesterone decreased (n/a - Recovering/Resolving -)	COMIRNATY COVID-19 MRNA VACCINE NUCLEOSIDE MODIFIED CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009148166	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])	ICSR
EU-EC-10009149075	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -), Vaginal discharge (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009149866	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Muscle twitching (n/a - Recovering/Resolving -), Uterine contractions abnormal (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALPHA-TOCOPHEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [BIOTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, VITAMIN B12] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [IODINE] (C - n/a - n/a - [n/a - n/a - n/a]), [NICOTINIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEGA-3 FATTY ACIDS] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOTHENIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RIBOFLAVIN] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009150183	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009151037	25/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Premature labour (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009151066	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009151673	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009151682	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009151680	25/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Infertility (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUPROPION HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009152271	25/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Abortion spontaneous (3d - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Maternal exposure during pregnancy (n/a - Unknown -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10009153156	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009154332	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009152021	24/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Stillbirth (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009127361	24/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Recovered/Resolved -), Placental disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Uterine spasm (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaginal haemorrhage (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009127363	24/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009129473	24/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Heavy menstrual bleeding (14d - Recovered/Resolved - Other Medically Important Condition), Premature menopause (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009130687	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown -), Injection site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009133419	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Asthenia (n/a - Recovered/Resolved -), Threatened labour (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, FERROUS SULFATE, DRIED FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009133479	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009135786	24/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009137370	24/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Accidental exposure to product (n/a - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Terminal insomnia (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009111104	23/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009112350	23/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Macrophthalmia (n/a - Fatal - Results in Death, Congenital Anomaly), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital Anomaly), PTEN gene mutation (n/a - Fatal - Results in Death, Congenital Anomaly), Stillbirth (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10009113933	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009117945	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009118757	23/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Foetal heart rate increased (n/a - Recovered/Resolved - Other Medically Important Condition), Foetal hypokinesia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009118779	23/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Foetal growth restriction (n/a - Fatal - Results in Death, Other Medically Important Condition), Foetal heart rate abnormal (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009119149	23/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009119459	23/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -), Menstruation delayed (n/a - Not Recovered/Not Resolved -), Pregnancy (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[PARACETAMOL] (C - Hangover - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009120387	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dyskinesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal death (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stillbirth (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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-10009097761	22/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Petechiae (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009097938	22/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash erythematous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009103558	22/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10009103591	22/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009103737	22/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (7d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Gastrointestinal haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition), Gestational diabetes (n/a - Recovered/Resolved - Other Medically Important Condition), Pregnancy with contraceptive device (n/a - Recovered/Resolved - Other Medically Important Condition), Pregnancy with implant contraceptive (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, NORGESTIMATE] (C - Contraception - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [VITAMINS NOS] (C - Pregnancy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009103746	22/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009103889	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009104420	22/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Uterine contractions abnormal (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009104427	22/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009105320	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	[CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009108343	22/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10009083243	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovering/Resolving - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009084488	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009085226	21/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009085262	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009085782	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10009085797	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Maternal exposure timing unspecified (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009086700	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Pain in extremity (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009086882	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Muscle spasms (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Primigravida (n/a - Recovering/Resolving - Other Medically Important Condition), Vaginal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ESTRADIOL] (C - In vitro fertilisation - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [PROGESTERONE, PROGESTERONE, MICRONISED] (C - In vitro fertilisation - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009088229	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009089524	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10009089923	21/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	Yes	Foetal death (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009091852	21/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10009093455	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle spasms (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neonatal disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009067172	18/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009072280	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Foetal growth restriction (n/a - Fatal - Results in Death, Congenital Anomaly), Foetal heart rate abnormal (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental]), [OMEPRAZOLE] (C - n/a - n/a - [1d - 10mg - Transplacental - More in ICSR]), [VITAMINS NOS] (C - Pregnancy - n/a - [n/a - n/a - Transplacental])	ICSR
EU-EC-10009047730	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009052445	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Abortion spontaneous (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DROTAVERINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [LUTEIN] (C - n/a - n/a - [n/a - n/a - n/a]), [PROGESTERONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009054271	17/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10009055507	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Anembryonic gestation (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009057531	17/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Premature baby (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009032918	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Female	Yes	Foetal growth restriction (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10009033324	16/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Pregnancy, Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009039881	16/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion early (31d - Recovered/Resolved With Sequelae -), Pyrexia (1d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009040683	16/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Gestational diabetes (n/a - Unknown - Other Medically Important Condition), Mass (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition), Skin warm (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009043440	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Adult	Female	No	Abortion (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Retroplacental haematoma (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009019007	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10009019254	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	COVID-19 VACCINE AZTRAZENACA (CHADOX1 NCOV-19) [COVID-19 VACCINE AZTRAZENACA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009019590	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal death (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009022872	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (7d - Recovered/Resolved -), Influenza like illness (7d - Recovered/Resolved -), Nausea (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009025571	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009026239	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009026241	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Recovered/Resolved - Other Medically Important Condition), Uterine contractions abnormal (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009027212	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Premature delivery (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Retroplacental haematoma (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009027482	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009027271	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[LEVOGLUTAMIDE, POLAPREZINC] (C - n/a - n/a - [n/a - n/a - n/a]), [NETTLE LEAF] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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
										Off label use (n/a - Unknown -).			
EU-EC-10009029489	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	18-64 Years	Female	Yes	Premature rupture of membranes (n/a - Recovered/Resolved - Other Medically Important Condition) Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Foetal growth restriction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10009029823	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009004355	14/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Accidental exposure to product (n/a - Unknown - Other Medically Important Condition), Allergy to chemicals (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heavy menstrual bleeding (5d - Recovered/Resolved - Other Medically Important Condition), Lymphadenopathy (3d - Recovered/Resolved - Other Medically Important Condition), Pregnancy on oral contraceptive (n/a - Unknown - Other Medically Important Condition), Rash pruritic (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NORETHISTERONE] (C - Contraception - n/a - [394d - n/a - n/a])	ICSR
EU-EC-10009004575	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Premature separation of placenta (n/a - Unknown - Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000907596	14/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-1000910606	14/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (162h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE, LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM ANHYDROUS EP] (C - Hypothyroidism - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-1000910824	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion (5d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000910830	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000911184	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Complication of pregnancy (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2s - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000911363	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000915184	14/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (37d - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000903606	13/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown -), Overdose (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000895422	12/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008980132	11/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal cystic hygroma (88d - Recovered/Resolved - Congenital Anomaly), Hydrops foetalis (88d - Recovered/Resolved - Congenital Anomaly), Trisomy 21 (88d - Recovered/Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000898067	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008981478	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008981581	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	IRON [IRON] (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])	ICSR
EU-EC-1000898016	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-1000898026	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000898033	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Foetal death (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000898082	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000898977	11/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(D)F - Intramuscular])	Not reported	ICSR
EU-EC-1000890456	11/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	No	No	Abortion spontaneous (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Pregnancy with implant contraceptive (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000894786	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (n/a - Unknown -), Chills (n/a - Unknown -), Erythema (n/a - Unknown -), Feeling hot (n/a - Unknown -), Headache (n/a - Unknown -), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Labour pain (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -), Pruritus (n/a - Unknown -), Pyrexia (n/a - Unknown -), Swelling (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008964571	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008970857	10/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Gestational diabetes (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving -), Maternal exposure during pregnancy (n/a - Unknown -), Vaccination site pain (1d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[ASCORBIC ACID, BETACAROTENE, COLECALCIFEROL, CYANOCOBALAMIN, FOLIC ACID, NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, ZINC, CALCIUM, COPPER, IODINE, IRON, MAGNESIUM, PANTOTHENIC ACID, PYRIDOXINE HYDROCHLORIDE, D ALPHA TOCOPHERYL ACETATE, ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, RIBOFLAVIN, CALCIUM, COPPER, IODINE, IRON, MAGNESIUM, PYRIDOXINE HYDROCHLORIDE, VITAMIN B12] (C - n/a - n/a - [n/a - n/a - 1(D)F - n/a])	ICSR
EU-EC-10008972493	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 8mL - Intramuscular])	Not reported	ICSR
EU-EC-10008972496	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Anembryonic gestation (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008974464	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Foetal death (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008952553	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008954306	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Premature rupture of membranes (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008955932	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Unknown -), Somnolence (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CYCLIZINE] (C - Nausea - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [PARACETAMOL] (C - Pregnancy with advanced maternal age - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008958286	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (42d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008958298	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Petechiae (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008959144	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Uterine contractions during pregnancy (2d - Recovered/Resolved - Other Medically Important Condition), Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008961386	09/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemorrhage in pregnancy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008961648	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10008962549	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008963394	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (n/a - Unknown - Other Medically Important Condition), Maternal exposure timing unspecified (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-1000896386	08/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[FOLIC ACID] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008937607	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10008940052	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Foetal growth restriction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure before pregnancy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008942476	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Unknown - Caused/Prolonged Hospitalisation), Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure timing unspecified (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10008943429	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Drug exposure before pregnancy (n/a - Unknown - Other Medically Important Condition), Extra dose administered (n/a - Unknown -), Inappropriate schedule of product administration (n/a - Unknown -), Pregnancy on contraceptive (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008947603	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Human chorionic gonadotropin increased (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008923889	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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-1000892674	07/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Off label use (n/a - Unknown -) Pregnancy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	NON SPECIFIED ANTICONCEPTIVUM (NOT AVAILABLE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008926163	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Eruressis (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008931397	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008933341	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Amniotic cavity infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown -), Fatigue (n/a - Unknown -), Foetal death (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown -), Pain (n/a - Unknown -), Perinatal depression (n/a - Unknown - Other Medically Important Condition), Premature labour (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Staphylococcal infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - Pregnancy - n/a - [n/a - n/a - n/a]), [CRISABOROLE] (C - Dermatitis atopic - n/a - [n/a - n/a - Topical]), [LORATADINE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008922016	06/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008914042	05/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Maternal exposure during pregnancy (n/a - Unknown -), Premature baby (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000891148	04/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cervix dystocia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Premature labour (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100089402	04/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-1000897339	04/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-1000898706	04/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neck mass (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000898713	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion (n/a - Unknown - Other Medically Important Condition), Vaginal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008989115	04/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (48h - Recovered/Resolved - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Headache (8d - Recovered/Resolved - Other Medically Important Condition), Morning sickness (2d - Recovered/Resolved - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Nausea (2d - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (2d - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (2d - Recovered/Resolved - Other Medically Important Condition), Sinusitis (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008901287	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [31d - 2(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008901346	04/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008901883	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008902170	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000897942	03/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000891091	03/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-1000894956	03/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008985157	03/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008987560	03/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008986050	02/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (8d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000894357	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Epistaxis (1d - Recovered/Resolved -), Gestational diabetes (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Folate deficiency - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008989407	02/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Product supply issue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 50ug - Oral])	ICSR
EU-EC-1000897265	02/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008955947	01/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008957048	01/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Stillbirth (2d - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008957900	01/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Back pain (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Pelvic pain (n/a - Not Recovered/Not Resolved -), Uterine contractions abnormal (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intravenous drip])	Not reported	ICSR
EU-EC-10008958907	01/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008937201	31/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008939740	31/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (8d - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008940424	31/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008942617	31/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Yes	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008945059	31/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Morning sickness (1d - Recovered/Resolved - Other Medically Important Condition), Vertigo (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008915012	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008917297	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ectopic pregnancy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008917308	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008917553	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Haemorrhage (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Premature labour (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation), Thrombosis (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008920170	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Uterine contractions during pregnancy (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008920188	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Uterine contractions during pregnancy (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008922508	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Death (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition), Meconium aspiration syndrome (n/a - Unknown - Other Medically Important Condition), Premature baby (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR])	[CRISABOROLE] (C - Dermatitis atopic - n/a - [n/a - n/a - Transplacental]), [LORATADINE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10008922734	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Recovering/Resolving - Other Medically Important Condition), Abortion missed (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Muscle spasms (n/a - Unknown - Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [CYCLIZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [MISOPROSTOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Headache - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008924081	28/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Neonate (Preterm and Term newborns)	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Unknown - Life Threatening), Premature baby (n/a - Unknown - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008979786	27/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008900746	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (3d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - Dose not changed - [n/a - n/a - n/a])	ICSR
EU-EC-10008900747	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008900776	27/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition), Abortion spontaneous (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Cough (n/a - Unknown - Congenital Anomaly), Foetal heart rate abnormal (n/a - Unknown -), Foetal hypokinesia (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition),	COVID-19 VACCINE ASTRAZENACA (CHADOX1 NCOV-19) (COVID-19 VACCINE ASTRAZENACA (CHADOX1 NCOV-19)) (S - n/a - Unknown - [n/a - n/a - n/a]), [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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
										Headache (n/a - Unknown - Congenital Anomaly), Maternal exposure during pregnancy (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Congenital Anomaly)			
EU-EC-10008607866	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Arrested labour (n/a - Recovering/Resolved - Other Medically Important Condition), Arthralgia (n/a - Recovering/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008784170	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008784198	26/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008785387	26/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Unknown - Other Medically Important Condition), Abortion spontaneous (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Haemorrhage (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008790778	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [1d - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10008794570	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008767142	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008767260	25/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CODEINE PHOSPHATE BP, PARACETAMOL PH. EUR., PARACETAMOL, CODEINE PHOSPHATE] (C - Pain - n/a - [n/a - n/a - n/a]), [CYCLIZINE] (C - Nausea - n/a - [n/a - n/a - n/a]), [FLUXETINE, FLUXETINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a]), [MEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008768118	25/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008768740	25/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008770918	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Neonatal pneumothorax (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Neonatal respiratory distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Premature baby (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])	ICSR
EU-EC-10008774181	25/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008774510	25/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Other Medically Important Condition), Dysmenorrhoea (n/a - Recovering/Resolved - Other Medically Important Condition), Haemorrhage (n/a - Recovering/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008778877	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ectopic pregnancy (n/a - Recovering/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008757944	24/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), Vaginal haemorrhage (n/a - Recovering/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008762267	24/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown -), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008754984	23/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FLUDROCORTISONE] (C - Adrenogenital syndrome - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [PREDNISOLONE] (C - Adrenogenital syndrome - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008725860	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion complete (10d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10008732908	21/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008737623	21/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Abortion (n/a - Unknown - Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008741647	21/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Foetal growth restriction (n/a - Fatal - Results in Death, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[ESTRADIOL] (C - n/a - n/a - [n/a - n/a - Transplacental]), [PROGESTERONE] (C - n/a - n/a - [n/a - n/a - Transplacental])	ICSR
EU-EC-10008712232	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition), Foetal growth restriction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008715513	20/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008717158	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[URSODEOXYCHOLIC ACID] (C - Cholestasis of pregnancy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008718506	20/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PROGESTERONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008718772	20/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Premature baby (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[DIPHTheria AND TETANUS TOXOIDS AND PERTUSSIS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008720869	20/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion early (5d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008721201	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Haemorrhage in pregnancy (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[DYDROGESTERONE] (C - High risk pregnancy - n/a - [21d - n/a - n/a - More in ICSR]), [SULFASALAZINE] (C - Rheumatic disorder - n/a - [n/a - 2000mg - n/a])	ICSR
EU-EC-10008721224	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Pre-eclampsia (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008721245	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008723677	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Accidental exposure to product (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008707435	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008710122	19/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008684204	18/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Premature baby (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Transplacental]), [ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - Transplacental]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Transplacental])	ICSR
EU-EC-10008691934	18/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (26d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008693613	18/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008694721	18/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008678866	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10008680159	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	No	Foetal growth restriction (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008660198	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Disabling, Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008681660	17/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion induced (n/a - Recovered/Resolved - Other Medically Important Condition), Foetal death (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10008655693	15/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Benign hydatidiform mole (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008646638	14/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Burning sensation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oedema peripheral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008649022	14/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Pelvic pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008632524	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008632584	13/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal hypokinesia (n/a - Recovering/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolved -), Maternal exposure during pregnancy (n/a - Recovering/Resolved -), Pain (n/a - Recovering/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008639390	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Premature labour (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaginal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008640551	13/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolved - Life Threatening, Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Life Threatening), Vaginal haemorrhage (n/a - Unknown - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - Pregnancy - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008640559	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008621068	12/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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-10008621334	12/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mood altered (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008621346	12/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008623733	12/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (7d - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Recovered/Resolved - Other Medically Important Condition), Vaginal haemorrhage (337h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - Anxiety - n/a - [723d - 10mg - Oral])	ICSR
EU-EC-10008625872	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Spine malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2[DF] - Intramuscular])	[CLOMIFENE CITRATE] (C - n/a - Not applicable - [n/a - n/a - n/a])	ICSR
EU-EC-10008626853	12/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008627256	12/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008627322	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008628935	12/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10008629534	11/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 125mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - n/a])	ICSR
EU-EC-10008629040	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - n/a])	Not reported	ICSR
EU-EC-10008610879	11/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Haematuria (n/a - Recovering/Resolving - Other Medically Important Condition), Uterine contractions abnormal (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10008611367	11/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [PARACETAMOL] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10008612508	11/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008612921	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Neonate (Preterm and Term newborns)	Male	Yes	Death neonatal (n/a - Fatal - Results in Death), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Premature baby (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Transplacental])	[ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Supplementation therapy - n/a - [n/a - 1[DF] - n/a]), [ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - Pregnancy - n/a - [n/a - 1[DF] - n/a]), [CALCIUM CARBONATE, CALCIUM CARBONATE PH. EUR.] (C - Gastroesophageal reflux disease - n/a - [n/a - 500mg - n/a]), [FLUTICASON PROPRIONATE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [TRIAMCINOLONE] (C - Dermatitis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008613859	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008619008	10/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	FIASP [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008619179	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral])	ICSR
EU-EC-10008619318	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008619905	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Uterine contractions abnormal (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10008619913	10/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - n/a])	CERTOLIZUMAB PEGOL [CERTOLIZUMAB PEGOL] (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, FORMOTEROL FLUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008620409	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abortion spontaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a - More in ICSR])	ICSR
EU-EC-10008620424	10/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008620434	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 800mg - n/a]), [GRATADINE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a]), [ENOXAPARIN] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008626740	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Female	No	Escherichia bacteraemia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Unknown -), Ovarian vein thrombosis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Postpartum haemorrhage (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Premature separation of placenta (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vulvovaginal injury (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008626910	07/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion threatened (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Blood glucose abnormal (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved -), Foetal death (n/a - Unknown - Other Medically Important Condition), Vertigo (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLIPIZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MECLOZINE HYDROCHLORIDE] (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 - n/a])	ICSR
EU-EC-10008626911	07/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly), Bell's palsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008629411	06/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008629240	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008629243	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Fatigue (n/a - Unknown -), Inappropriate schedule of product administration (n/a - Unknown -), Off label use (n/a - Unknown -), Pyrexia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008629287	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008629299	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Foetal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation, Congenital Anomaly), Premature baby (n/a - Unknown - Caused/Prolonged Hospitalisation, Congenital Anomaly), Tachycardia foetal (n/a - Unknown - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008630473	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008615464	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cervical incompetence (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008618439	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008610306	01/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Morning sickness (1d - Recovered/Resolved -), Sleep disorder (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008475092	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (46d - Recovered/Resolved - Other Medically Important Condition), Arthralgia (46d - Recovered/Resolved - Other Medically Important Condition), Bone pain (46d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (46d - Recovered/Resolved - Other Medically Important Condition), Fatigue (46d - Recovered/Resolved - Other Medically Important Condition), Headache (46d - Recovered/Resolved - Other Medically Important Condition), Oxygen saturation decreased (46d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (46d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [1d - 3mL - Intramuscular]), [S-METHYLETHANEDIUM DIHYDROGEN PHOSPHATE, CALCIUM FOLINATE PENTAHYDRATE, LEVOMEFOLATE, CALCIUM] (S - n/a - Unknown - [n/a - n/a - n/a]), [ANHYDROUS AZITHROMYCIN, AZITHROMYCIN, AZITHROMYCIN DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008475832	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008478451	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Asthma (n/a - Unknown -), Headache (n/a - Unknown -), Pruritus (n/a - Unknown -), Swelling (n/a - Unknown -), Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008481659	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [26d - 2[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10008482913	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008485605	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion (12d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008485914	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008480424	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008487572	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion threatened (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Retrolacental haematoma (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	[VITAMINS NOS] (C - Pregnancy - n/a - [72d - n/a - n/a])	ICSR
EU-EC-10008470713	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008484843	27/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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-10008433557	27/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008457576	27/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (5d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008458358	27/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Intermenstrual bleeding (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-1000847235	26/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	NO DRUG [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008473904	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - n/a])	Not reported	ICSR
EU-EC-10008440040	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition), Intermenstrual bleeding (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008440568	26/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vaginal haemorrhage (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008445095	26/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[MESALAZINE] (C - Colitis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008429275	25/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008409462	23/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008394991	22/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Foetal growth restriction (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10008399021	22/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Gingival pain (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia oral (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Mouth swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oral mucosal erythema (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM] (C - Abortion spontaneous - n/a - [1d - n/a - n/a]), [FOLIC ACID] (C - Pregnancy, Vitamin supplementation - n/a - [50d - n/a - n/a - More in ICSR]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hyperthyroidism - n/a - [n/a - n/a - n/a]), [MISOPROSTOL] (C - Abortion spontaneous - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10008399441	22/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Gestational diabetes (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved -), Hyperglycaemia (36h - Recovered/Resolved -), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [VITAMINS NOS] (C - Pregnancy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008401635	22/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (n/a - Unknown -), Foetal death (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[TRANEXAMIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008382095	21/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Disabling, Other Medically Important Condition), Chills (n/a - Unknown - Disabling), Maternal exposure during pregnancy (n/a - Unknown - Disabling), Neck pain (n/a - Unknown - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Post procedural hypothyroidism - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008387179	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown -), Off label use (n/a - Unknown -), Pregnancy (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [NITROFURANTOIN] (C - Urinary tract infection - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008385501	21/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008385576	21/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Yes	Yes	Foetal heart rate disorder (n/a - Recovering/Resolving - Other Medically Important Condition), Neonatal respiratory acidosis (n/a - Recovering/Resolving -), Premature baby (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008389288	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Arrested labour (n/a - Not Recovered/Not Resolved -), Blood pressure increased (n/a - Not Recovered/Not Resolved -), Influenza like illness (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Vertigo (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008373449	20/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Male	Yes	Exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Premature baby (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008354885	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008355934	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Yes	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008359227	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10008363249	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008353951	18/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008340597	17/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10008325487	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Male	Yes	Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Premature baby (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory disorder neonatal (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008311507	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[PROGESTERONE, PROGESTERONE, MICRONISED] (C - Progesterone decreased - n/a - [1d - n/a - Vaginal])	ICSR
EU-EC-10008313443	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008313443	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CABERGOLINE] (C - Macroprolactinaemia - n/a - [5003d - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008323270	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Unknown - Life Threatening), Premature baby (n/a - Unknown - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008300406	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Menstruation delayed (n/a - Unknown -), Pregnancy with contraceptive device (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AMITRIPTYLINE, AMITRIPTYLINE HYDROCHLORIDE] (C - Headache - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008301549	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Vaginal haemorrhage (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - Prenatal care - n/a - [n/a - n/a - Oral]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Anxiety, Depression - n/a - [n/a - 20mg - Oral]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Anxiety, Depression - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008309131	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (3d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Abortion spontaneous (3d - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008309678	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -), Off label use (n/a - Unknown -), Pre-eclampsia (3d - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation), Product use issue (n/a - Unknown -), Protein urine present (n/a - Unknown -), Weight increased (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ENOXAPARIN, ENOXAPARIN SODIUM] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008287911	13/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008288464	13/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Foetal growth restriction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008288482	13/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Foetal growth restriction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008289562	13/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Maternal exposure before pregnancy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008290923	13/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10008296999	13/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008298397	13/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Anthralgia (3d - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), Myalgia (3d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 3mL - Intramuscular])	[DICYCLVERINE HYDROCHLORIDE, DOXYLAMINE HYDROGEN SUCCINATE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10008274883	12/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Exposure during pregnancy (n/a - Unknown -), Premature rupture of membranes (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008290348	12/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10008281492	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10008286192	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Intermenstrual bleeding (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008250209	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10008256837	09/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Pregnancy, Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes Economic Area	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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							Dizziness (40d - Recovered/Resolved - Other Medically Important Condition), Illness (39d - Recovered/Resolved - Other Medically Important Condition), Inner ear disorder (39d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure before pregnancy (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10008234622	08/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008236768	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008240520	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008241206	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008243569	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008246387	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Stillbirth (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008214236	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Twin pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008216467	07/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008220755	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (7d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - n/a])	Not reported	ICSR
EU-EC-10008220853	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Abortion spontaneous (n/a - Recovering/Resolving - Congenital Anomaly, Other Medically Important Condition), Chills (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition), Nausea (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008222134	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Injection site pain (n/a - Unknown -), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - n/a])	Not reported	ICSR
EU-EC-10008224193	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - n/a])	Not reported	ICSR
EU-EC-10008227171	07/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008209603	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (4d - Recovered/Resolved - Other Medically Important Condition), Accidental exposure to product (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008211376	06/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008213373	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ACICLOVIR, ACICLOVIR SODIUM] (C - n/a - n/a - [n/a - 400mg - Oral])	ICSR
EU-EC-10008193682	05/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (14d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008197220	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - n/a])	Not reported	ICSR
EU-EC-10008198996	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IRON [IRON] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008201985	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008176645	03/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(DF) - Intramuscular])	Not reported	ICSR
EU-EC-10008168754	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 3mL - Intramuscular])	[CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLURAZEPAM MONOHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008172993	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Yes	Foetal death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal heart rate abnormal (n/a - Unknown - Other Medically Important Condition), Foetal movement disorder (n/a - Unknown - Other Medically Important Condition), Syndactyly (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008158070	01/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthma (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood creatinine abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood creatinine increased (n/a - Not Recovered/Not Resolved -), Blue toe syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Body temperature decreased (n/a - Unknown - Other Medically Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema of eyelid (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eyelids pruritus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gait disturbance (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Influenza like illness (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of personal independence in daily activities (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Morning sickness (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Near death experience (n/a - Unknown - Other Medically Important Condition), Pallor (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Photosensitivity reaction (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhinitis (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown -), Swelling of eyelid (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	DULOXETINE HYDROCHLORIDE [DULOXETINE HYDROCHLORIDE] (C - Anxiety, Pain - n/a - [n/a - 60mg - Oral]), [ASCORBIC ACID, CALCIUM ASCORBATE] (C - n/a - n/a - [n/a - 1000(U) - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1000(U) - Oral]), [FISH OIL] (C - Cardiovascular event prophylaxis - n/a - [n/a - 1000(U) - Oral]), [HYDROCHLOROTHIAZIDE, LISINAPRIL] (C - Hypertension - n/a - [n/a - n/a - Oral]), [LANSOPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - 30mg - Oral]), [LINSEED OIL] (C - Cardiovascular event prophylaxis - n/a - [n/a - 1000(U) - Oral]), [LORAZEPAM] (C - Anxiety - n/a - [n/a - n/a - Oral]), [MELOXICAM] (C - Back disorder - n/a - [n/a - 15mg - n/a])	ICSR
EU-EC-10008158777	01/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (0d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Exposure during pregnancy (n/a - Recovering/Resolving -), Vaccination site pain (48h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008166651	01/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly), Decreased embryo viability (n/a - Recovered/Resolved - Congenital Anomaly), Haemorrhage in pregnancy (n/a - Recovered/Resolved - Congenital Anomaly)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Pregnancy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008147034	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(DF) - Intramuscular])	Not reported	ICSR
EU-EC-10008150567	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	Yes	Foetal death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC-10008131255	30/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ectopic pregnancy (33d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008131943	30/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008133513	30/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008138886	30/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008128368	29/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Bursitis (n/a - Recovering/Resolving - Other Medically Important Condition), Pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008118050	28/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (5d - Recovered/Resolved -), Maternal exposure during breast feeding (n/a - Unknown -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[FLUTICASON PROPRIONATE, SALMETEROL, FLUTICASON PROPRIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008116576	27/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008084893	26/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (2d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Pain (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a]), [DROSPIRENONE, ETHINYLESTRADIOL, DROSPIRENONE, ETHINYLESTRADIOL BETADE CLATHRATE, LACTOSE, LACTOSE MONOHYDRATE] (C - Contraception - n/a - [4Z/d - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008089692	26/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Limb discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Morning sickness (n/a - Unknown - Other Medically Important Condition), Motion sickness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008067409	25/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008053092	24/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AZATHIOPRINE] (C - Immunosuppression - n/a - [n/a - n/a - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes Economic Area	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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
										Chills (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Morning sickness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10008057320	24/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008039894	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemorrhage (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10008039752	23/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Morning sickness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neck pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Night sweats (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000804699	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008046622	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008026864	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Chilblains (n/a - Unknown -), Fatigue (2d - Recovered/Resolved -), Maternal exposure during pregnancy (n/a - Unknown -), Oropharyngeal pain (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10007990277	19/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007990520	19/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000797811	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1mo - 3ml - Intramuscular])	Not reported	ICSR
EU-EC-1000797884	19/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oligohydramnios (n/a - Unknown - Caused/Prolonged Hospitalisation), Premature rupture of membranes (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10007976010	18/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Uterine contractions during pregnancy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007976494	18/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Arthralgia (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10007978119	18/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [PARACETAMOL] (C - Pyrexia - n/a - [2d - n/a - n/a])	ICSR
EU-EC-10007978365	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10007984034	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007967722	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (37d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007969557	17/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	STELARA [LUSTEKINUMAB] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007944126	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ectopic pregnancy (1d - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Headache - n/a - [n/a - n/a - Oral]), [ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007947838	16/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Adult	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007929544	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Chills (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -)	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])	ICSR
EU-EC-10007932088	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (0d - Unknown - Other Medically Important Condition), Body temperature increased (3d - Recovered/Resolved -), Injection site inflammation (3d - Recovered/Resolved -), Injection site pain (4d - Recovered/Resolved -), Myalgia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 3ml - Intramuscular])	Not reported	ICSR
EU-EC-10007934892	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Anembryonic gestation (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -), Myalgia (n/a - Recovered/Resolved -)	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]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007935586	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Astenopia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Disturbance in attention (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Nuchal rigidity (n/a - Not Recovered/Not Resolved -), Previous caesarean section (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	[LEVOTHYROXINE SODIUM] (C - n/a - Not applicable - [n/a - n/a - n/a])	ICSR
EU-EC-1000790287	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Accidental exposure to product (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007898074	11/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10007892801	11/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (10d - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Morning sickness (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Headache - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007873327	10/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007874147	10/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLATE SODIUM] (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]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007874153	10/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (0d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CETIRIZINE DIHYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - 1(Df) - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - 1(Df) - n/a])	ICSR
EU-EC-10007874182	10/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (n/a - Unknown - Other Medically Important Condition), Bladder pain (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dysuria (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Infection (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Presyncope (n/a - Unknown - Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Other Medically Important Condition), Urine odour abnormal (n/a - Unknown - Other Medically Important Condition), Uterine contractions abnormal (n/a - Unknown - Other Medically Important Condition), Uterine pain (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007886667	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (1d - Recovered/Resolved - Other Medically Important Condition), Exposure during pregnancy (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Unknown])	Not reported	ICSR
EU-EC-10007857925	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -)	Not reported	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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	Non European Economic Area	Not available	Years	Specified				[n/a - 30ug - Intramuscular]		
EU-EC-1000786388	09/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Disease recurrence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haemorrhoids (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Morning sickness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Throat irritation (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[GLUCOSAMINE SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [THYROXINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000786478	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Yes	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000786427	08/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), COVID-19 (13d - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (11d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL FUMARATE] (C - Heart rate - n/a - [563d - n/a - n/a]), [CARBIMAZOLE] (C - Hypert thyroidism - n/a - [829d - n/a - n/a]), [CYCLIZINE] (C - Vomiting - n/a - [3d - n/a - n/a]), [FLECAINIDE, FLECAINIDE ACETATE] (C - Arrhythmia - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-1000778360	05/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (11d - Recovered/Resolved - Other Medically Important Condition), Pain (1d - Recovered/Resolved - Other Medically Important Condition), Paresthesia (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000780648	05/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Premature delivery (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Preterm premature rupture of membranes (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID] (C - Pregnancy - n/a - [n/a - n/a - n/a]), [DALTEPARIN SODIUM] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000788187	05/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Back pain (2d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure before pregnancy (n/a - Unknown - Other Medically Important Condition), Pain in extremity (5d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYSALICYLIC ACID] (C - Pregnancy - n/a - [n/a - n/a - n/a]), [DALTEPARIN SODIUM] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007786286	04/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Foetus	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Premature baby (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[ACETYSALICYLIC ACID] (C - Pregnancy - n/a - [n/a - n/a - n/a]), [DALTEPARIN SODIUM] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a]), [INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007788452	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10007775447	03/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Morning sickness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Parosmia (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[OMEPRAZOLE] (C - Diverticulitis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007782372	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Maternal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1(Df) - n/a])	[BUDESONIDE] (C - Asthma - n/a - [n/a - 200ug - Respiratory (inhalation)]), [FLUTICASON PROPRIONATE] (C - Rhinorrhoea - n/a - [1485d - 100ug - Nasal]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - 10mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - 200ug - Respiratory (inhalation)]), [BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [412d - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10007786304	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (6d - Recovered/Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [412d - n/a - n/a]), [FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10007767750	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007788546	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain upper (1d - Recovered/Resolved - Other Medically Important Condition), Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (3d - Recovered/Resolved - Other Medically Important Condition), Migraine (2d - Recovered/Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Analgesic therapy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007741321	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007723765	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007726372	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion missed (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007711980	24/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Morning sickness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007715243	24/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (6d - Recovered/Resolved - Other Medically Important Condition), COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10007692986	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10007694555	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Morning sickness (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition), Productive cough (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007698442	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007701116	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR
EU-EC-10007701264	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	High risk pregnancy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007688219	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007627468	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Foetal death (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - 150mg - n/a - More in ICSR])	ICSR
EU-EC-10007622842	15/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (1d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - n/a - n/a -)	ICSR
EU-EC-10007554747	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (1d - Recovered/Resolved -), Maternal exposure during pregnancy (n/a - Unknown -)	[TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007554924	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Yes	Abortion spontaneous (228h - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007540920	07/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007527372	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovering/Resolving - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007516464	04/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion spontaneous (2d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007470768	29/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Congenital Anomaly), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007444990	27/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007421335	25/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Abortion (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007394592	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion missed (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1000737441	19/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Congenital Anomaly), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AZELASTINE HYDROCHLORIDE, FLUTICASON PROPRIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007377494	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Maternal exposure during pregnancy (n/a - Unknown -), Pregnancy (n/a - Unknown -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007369445	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abortion spontaneous (n/a - Recovered/Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007326255	11/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Abortion spontaneous (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR