

## Line Listing Report

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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-10011130079	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011117905	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cold sweat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ear pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011119319	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Adrenal haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 immunisation (n/a - Unknown - Caused/Prolonged Hospitalisation), Foetal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytosis (2mo - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular])	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 1{DF} - n/a])	<a href="#">ICSR</a>
EU-EC-10011126489	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Sensory disturbance (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>

EU-EC-10011103857	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Pyrexia (n/a - Recovered/Resolved - ),  Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011111528	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Pyrexia (n/a - Recovered/Resolved - ),  Somnolence (1d - Recovered/Resolved - ),  Vomiting (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011093644	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Exposure via breast milk (n/a - Recovered/Resolved - ),  Nausea (n/a - Recovered/Resolved - ),  Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011098901	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Extrasystoles (n/a - Unknown - Other Medically Important Condition),  Incorrect route of product administration (n/a - Unknown - ),  Overdose (n/a - Unknown - ),  Product administered to patient of inappropriate age (n/a - Unknown - ),  Product preparation error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[COLECALCIFEROL, CALCIUM CITRATE] (C - Prophylaxis - n/a - [n/a - n/a - Oral]),  [PNEUMOCOCCAL POLYSACCHARIDE CONJUGATE VACCINE (13-VALENT, ADSORBED) CONJUGATED TO CRM197 CARRIER PROTEIN AND ADSORBED ON ALUMINIUM PHOSPHATE] (C - n/a - n/a - [1d - n/a - Intramuscular]),  [POLIOMYELITIS VACCINE (INACTIVATED)] (C - n/a - n/a - [1d - n/a - Intramuscular])	<a href="#">ICSR</a>
EU-EC-10011099764	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Nausea (3d - Recovered/Resolved - ),  Paraesthesia (3d - Recovered/Resolved - ),  Vomiting (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011099769	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Fatigue (1d - Recovered/Resolved - ),  Malaise (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10011100784	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10011081945	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary]),  SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown - More in ICSR])	Not reported	<a href="#">ICSR</a>
EU-EC-10011067728	24/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	2 Months	Not Specified	Not Specified	No	Exposure via breast milk (n/a - Unknown	COMIRNATY [TOZINAMERAN]	Not reported	<a href="#">ICSR</a>

				Area		- 2 Years				- ), Suspected COVID-19 (n/a - Unknown - )	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10011045330	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Peripheral sensory neuropathy (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10011047161	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Ear infection (3wk - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10011012827	20/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Angioedema (n/a - Unknown - Life Threatening, Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10011001264	18/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Crying (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010993544	17/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Somnolence (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010997013	17/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - ), Pneumonitis (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010982581	16/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Foetus	Female	Yes	Foetal death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010957214	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Constipation (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010962033	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Hypersensitivity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	IBRANCE 100 MG [PALBOCICLIB] (C - n/a - n/a - [n/a - n/a - Oral])	<a href="#">ICSR</a>
EU-EC-10010964223	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Cough (6d - Recovered/Resolved - ), Diarrhoea (6d - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010966084	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Restlessness (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary - More in ICSR])	Not reported	<a href="#">ICSR</a>

											Medically Important Condition)			
EU-EC-10010970281	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010952810	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Decreased appetite (6d - Recovered/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Vomiting (6d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010953185	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Cough (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])	<a href="#">ICSR</a>	
EU-EC-10010955230	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Headache (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[IBUPROFEN] (C - Teething - n/a - [n/a - n/a])	<a href="#">ICSR</a>	
EU-EC-10010955254	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010940528	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Influenza (2d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010940536	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010942668	13/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months	Not Specified	Not Specified	Yes	Exposure via breast milk (0d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	<a href="#">ICSR</a>	

				Economic Area		- 2 Years				- Other Medically Important Condition), Somnolence (0d - Recovered/Resolved - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - Transmammary])		
EU-EC-10010942766	13/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (0d - Recovered/Resolved - Other Medically Important Condition), Somnolence (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010932225	12/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  [CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, COLECALCIFEROL CONCENTRATE (OILY FORM)] (C - n/a - n/a - [n/a - 2000mg - Oral]),  [PREDNISOLONE] (C - n/a - n/a - [n/a - 5mg - Oral]),  [RAMIPRIL] (C - n/a - n/a - [n/a - 2.5mg - Oral])		<a href="#">ICSR</a>
EU-EC-10010922347	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Not Specified	Yes	Heart disease congenital (n/a - Fatal - Results in Death, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transplacental])	Not reported	<a href="#">ICSR</a>
EU-EC-10010927361	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Eczema infantile (n/a - Recovering/Resolving - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010928705	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Abdominal pain (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010906300	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infantile apnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Infantile vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

										Important Condition),  Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Pyrexia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010894537	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Asthenia (2d - Recovered/Resolved - ),  Lymphadenopathy (2d - Recovered/Resolved - ),  Rhinorrhoea (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular])	[CYAMEMAZINE] (C - n/a - n/a - [n/a - n/a - n/a]),  [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]),  [PANCREAS POWDER FROM PORCINE, PANCREATIN] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010899040	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ),  Malaise (3d - Recovered/Resolved - ),  Pyrexia (3d - Recovered/Resolved - ),  Sleep disorder (3d - Recovered/Resolved - ),  Vomiting (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010877909	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - ),  Exposure via breast milk (n/a - Not Recovered/Not Resolved - ),  Faeces discoloured (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010880497	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Premature baby (n/a - Unknown - Life Threatening, 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])	<a href="#">ICSR</a>
EU-EC-10010863260	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Insomnia (n/a - Unknown - Other Medically Important Condition),  Nasal congestion (n/a - Unknown - Other Medically Important Condition),  Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),  Ocular hyperaemia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

										Resolved - Other Medically Important Condition), Periorbital swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Screaming (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010870023	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (n/a - Recovering/Resolving - ), Weight decreased (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010870417	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Pyelitis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	<a href="#">ICSR</a>
EU-EC-10010848409	03/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nasal congestion (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (2d - Recovered/Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Screaming (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sleep disorder (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010834580	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010835150	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Fungal skin infection	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<a href="#">ICSR</a>

										(n/a - Unknown - ), Infant irritability (n/a - Unknown - ), Oral fungal infection (n/a - Unknown - ), Tongue fungal infection (n/a - Unknown - )	,3mL - Transmammary])		
EU-EC-10010800948	30/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Derealisation (n/a - Recovering/Resolving - ), Paraesthesia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010800955	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Body temperature increased (24h - Recovered/Resolved - ), Musculoskeletal stiffness (1h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010800967	30/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Headache (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - )	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]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010800984	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010800987	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Chills (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 - Recovering/Resolving - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010801779	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010801785	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Arthralgia (48h - Recovered/Resolved - ), Chills (24h - Recovered/Resolved - ), Constipation (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>



										Recovering/Resolving - ), Injection site pain (8h - Recovered/Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (3d - Recovered/Resolved - ), Pyrexia (24h - Recovered/Resolved - )			
EU-EC-10010801789	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Amenorrhoea (1mo - Recovered/Resolved - ), Fatigue (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PANTOPRAZOLE] (C - n/a - n/a - [n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010801798	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (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 - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[CITALOPRAM] (C - n/a - n/a - [n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010801804	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Not Recovered/Not Resolved - ), Injection site erythema (n/a - Recovering/Resolving - ), Injection site inflammation (n/a - Recovering/Resolving - ), Injection site pain (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010801816	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Arthralgia (1d - Recovered/Resolved - ), Chills (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Headache (0d - Recovered/Resolved - ), Malaise (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>

										Myalgia (n/a - Recovering/Resolving - ), Pyrexia (0d - Recovered/Resolved - )			
EU-EC-10010801819	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Acne (n/a - Recovering/Resolving - ), Back pain (n/a - Recovering/Resolving - ), Breast tenderness (n/a - Recovering/Resolving - ), Menstruation delayed (4d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010802609	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Abdominal discomfort (n/a - Recovering/Resolving - ), Abdominal distension (n/a - Recovering/Resolving - ), Amenorrhoea (35d - Recovered/Resolved - ), Fatigue (35d - Recovered/Resolved - ), Menstruation irregular (35d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010802619	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (1d - Recovered/Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010802623	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010802626	30/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Chills (2d - Recovered/Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (2d - Recovered/Resolved - ), Injection site inflammation (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - Dose not changed - [n/a - n/a - n/a]), [LITHIUM CARBONATE] (C - n/a - Dose not changed - [n/a - n/a - n/a])	<a href="#">ICSR</a>

											Injection site pain (2d - Recovered/Resolved - ), Injection site swelling (2d - Recovered/Resolved - ), Malaise (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - )			
EU-EC-10010786083	28/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Dizziness (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Migraine (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010769610	26/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Vomiting projectile (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010769810	26/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Crying (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010774707	26/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Vaccination failure (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010765108	25/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Malaise (n/a - Recovered/Resolved - ), Neonatal disorder (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary]) [IBUPROFEN] (C - n/a - n/a - [n/a - n/a - Transmammary]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010753028	24/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Injection site rash (n/a - Not Recovered/Not Resolved - ), Rash papular (n/a - Not Recovered/Not Resolved - ), Rash pruritic (n/a - Not Recovered/Not Resolved - ), Skin reaction (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010718206	23/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010716610	22/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - ), Haematemesis (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010701357	19/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Rash (19d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	

EU-EC-10010682417	18/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Cardiac failure (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Fluid retention (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pleural effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - Oral]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - Oral])	<a href="#">ICSR</a>
EU-EC-10010668451	17/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Abdominal pain (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010672391	17/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Abdominal pain (5d - Not Recovered/Not Resolved - ), Diarrhoea (5d - Recovered/Resolved - ), Exposure via breast milk (5d - Not Recovered/Not Resolved - ), Flatulence (5d - Not Recovered/Not Resolved - )	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010672730	17/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Faeces discoloured (n/a - Unknown - Other Medically Important Condition), Urine output decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010674139	17/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (n/a - Unknown - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010649507	15/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	Yes	Diarrhoea (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010614665	11/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Exposure via breast milk (n/a - Recovering/Resolving - Other Medically Important Condition), Petechiae (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR])	Not reported	<a href="#">ICSR</a>
EU-EC-10010620023	11/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Rash maculo-papular (12h - Recovered/Resolved)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

										- Other Medically Important Condition)			
EU-EC-10010603625	10/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Infantile vomiting (n/a - Recovered/Resolved - Other Medically Important Condition),  Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010611453	10/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - ),  Somnolence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010611951	10/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Anaphylactic reaction (36h - Recovered/Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Recovered/Resolved - Other Medically Important Condition),  Pyrexia (n/a - Recovered/Resolved - ),  Rash (n/a - Recovered/Resolved - Other Medically Important Condition),  Rash maculo-papular (36h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010585814	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Eruaction (n/a - Not Recovered/Not Resolved - ),  Exposure via breast milk (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010593125	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Asthenia (2d - Recovered/Resolved - ),  Diarrhoea (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010596420	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Dysentery (2d - Recovered/Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Infantile vomiting (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	[MENINGOCOCCAL GROUP B VACCINE] (C - n/a - n/a - [1d - n/a - Intramuscular]),  [N. MENINGITIDIS GROUP C POLYSACCHARIDE, N. MENINGITIDIS GROUP Y POLYSACCHARIDE, NEISSERIA MENINGITIDIS GROUP A POLYSACCHARIDE, NEISSERIA MENINGITIDIS GROUP W135 POLYSACCHARIDE, N. MENINGITIDIS GROUP C POLYSACCHARIDE, NEISSERIA MENINGITIDIS GROUP A	<a href="#">ICSR</a>

												POLYSACCHARIDE, NEISSERIA MENINGITIDIS GROUP W135 POLYSACCHARIDE, NEISSERIA MENINGITIDIS GROUP Y] (C - n/a - n/a - [1d - n/a - Intramuscular])	
EU-EC-10010597309	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010580137	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	Exposure during pregnancy (n/a - Recovered/Resolved - Other Medically Important Condition),  Rash maculo-papular (2wk - Recovered/Resolved - Other Medically Important Condition),  Rash pruritic (14d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010584720	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Recovered/Resolved - ),  Irritability (24h - Recovered/Resolved - ),  Nasopharyngitis (24h - Recovered/Resolved - ),  Rhinorrhoea (24h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010574630	07/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Flatulence (n/a - Recovering/Resolving - Other Medically Important Condition),  Infantile vomiting (n/a - Recovering/Resolving - Other Medically Important Condition),  Lethargy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010562040	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Pyrexia (n/a - Unknown - Other Medically Important Condition),  Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010562085	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Diarrhoea (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN]	[FLUCLOXACILLIN, FLUCLOXACILLIN	<a href="#">ICSR</a>

			Professional	Economic Area		- 2 Years					- Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infantile vomiting (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	SODIUM, FLUCLOXACILLIN SODIUM MONOHYDRATE] (C - Mastitis - n/a - [7d - n/a - n/a])	
EU-EC-10010570535	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Chest pain (n/a - Recovering/Resolving - ), Feeling hot (n/a - Recovering/Resolving - ), Haemorrhage (4d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010553551	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Breast milk substitute intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Lactose intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010539726	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010513457	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Dizziness (57d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (57d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (57d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	

											Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010515740	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010520787	02/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Metabolic syndrome (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 2{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010507258	01/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	Yes	Diarrhoea (n/a - Unknown - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010495332	30/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Nasopharyngitis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010481752	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Feeling hot (n/a - Not Recovered/Not Resolved - ), Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010487260	29/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010437034	26/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Food refusal (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010449874	26/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Rash papular (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010414536	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Infant irritability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Transmammary])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>	
EU-EC-10010414567	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	



											milk (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Viral infection (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10010420145	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - ), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infant irritability (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010421629	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Haematochezia (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010396602	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - ), Crying (n/a - Recovering/Resolving - ), Restlessness (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010397155	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010398444	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Discomfort (1d - Recovered/Resolved - ), Exposure via breast milk (1d - Recovered/Resolved - ), Poor feeding infant (1d - Recovered/Resolved - ), Restlessness (1d - Recovered/Resolved - ), Screaming (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010403342	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Not Specified	No	Somnolence (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-	22/10/2021	Spontaneous	Healthcare	Non	Not	2	Not	Female	Yes	Exposure via breast	TOZINAMERAN	Not reported	<a href="#">ICSR</a>	

10010404020			Professional	European Economic Area	available	Months - 2 Years	Specified				milk (n/a - Unknown - ), Serum sickness (n/a - Recovering/Resolving - Life Threatening)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])		
EU-EC-10010406408	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes		Exposure via breast milk (n/a - Unknown - ), Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010388101	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes		Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Haematochezia (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010388104	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes		Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010390964	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes		Off label use (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010391147	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	No		Foetal death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Transplacental])	[LABETALOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010391848	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No		Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010375840	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No		Asthmatic crisis (1d - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Breast swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010378677	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No		Abdominal pain (n/a - Not Recovered/Not Resolved - ), Constipation (n/a - Not Recovered/Not Resolved - ), Faeces discoloured (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Oral])	Not reported	<a href="#">ICSR</a>

EU-EC-10010379987	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010365013	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010352611	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Maternal exposure during breast feeding - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010342147	17/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Fever neonatal (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010340164	16/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Stupor (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010341195	16/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Nausea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010336958	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	No	Supernumerary nipple (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010337329	15/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal pain (n/a - Recovering/Resolving - ), Diarrhoea neonatal (n/a - Recovering/Resolving - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - ), Neonatal intestinal obstruction (n/a - Recovering/Resolving - Other Medically Important Condition), Screaming (7h - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010314503	14/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Somnolence (12h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010326411	14/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

										- Other Medically Important Condition)			
EU-EC-10010305904	13/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010308119	13/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Infantile vomiting (1d - Recovered/Resolved - Other Medically Important Condition),  Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Mucous stools (n/a - Unknown - Other Medically Important Condition),  Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Urine output decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010309295	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Crying (n/a - Recovering/Resolving - ),  Exposure via breast milk (n/a - Unknown - ),  Restlessness (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010309407	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Abnormal faeces (n/a - Recovered/Resolved - ),  Exposure via breast milk (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]),  [DESOGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010309882	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Cough (n/a - Unknown - ),  Exposure via breast milk (n/a - Unknown - ),  Fatigue (n/a - Unknown - ),  Malaise (n/a - Unknown - ),  Nasopharyngitis (n/a - Unknown - ),  Pyrexia (n/a - Unknown - ),  Somnolence (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010312642	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - )	Not reported	<a href="#">ICSR</a>

										Pyrexia (n/a - Unknown - )	Unknown - [1d - 1{DF} - Transmammary])		
EU-EC-10010287420	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Feeling jittery (n/a - Not Recovered/Not Resolved - ),  Maternal exposure timing unspecified (n/a - Not Recovered/Not Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010290232	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Cough (n/a - Unknown - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - ),  Infant irritability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Nasal congestion (n/a - Unknown - Other Medically Important Condition),  Respiratory tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Sneezing (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary]),  [CETIRIZINE DIHYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - Transmammary]),  [MOMETASONE FUROATE, MOMETASONE FUROATE MONOHYDRATE] (C - Seasonal allergy - n/a - [n/a - n/a - Transmammary]),  [PARACETAMOL] (C - Afterbirth pain - n/a - [n/a - n/a - Transmammary]),  [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Transmammary]),  [TRIMETHOPRIM] (C - Urinary tract infection - n/a - [n/a - n/a - Transmammary])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Afterbirth pain - n/a - [n/a - n/a - Transmammary]),	<a href="#">ICSR</a>
EU-EC-10010291581	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Eczema infantile (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Infant sedation (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010292619	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Hypotonia (n/a - Not Recovered/Not Resolved - Life Threatening),  Maternal exposure during pregnancy (n/a - Unknown - ),  Neonatal asphyxia (n/a - Not Recovered/Not Resolved - Life Threatening),  Tremor (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010293832	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-	12/10/2021	Spontaneous	Non	Non	Not	2	Not	Female	Yes	Abdominal	TOZINAMERAN	Not reported	<a href="#">ICSR</a>

10010294311			Healthcare Professional	European Economic Area	available	Months - 2 Years	Specified			discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - ), Faeces discoloured (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infant irritability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urine ketone body present (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])		
EU-EC-10010295088	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Erythema nodosum (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Night sweats (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010295121	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Accidental exposure to product by child (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Urticaria (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	<a href="#">ICSR</a>
EU-EC-10010297334	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<a href="#">ICSR</a>

										Rash (1d - Recovered/Resolved - Other Medically Important Condition), Rash neonatal (n/a - Unknown - Other Medically Important Condition)	n/a - Transmammary}}		
EU-EC-10010298220	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Acoustic stimulation tests abnormal (n/a - Unknown - Other Medically Important Condition), Jaundice neonatal (n/a - Not Recovered/Not Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Transplacental]), [ACRIVASTINE, DIPHENHYDRAMINE, DIPHENHYDRAMINE HYDROCHLORIDE, DIPHENHYDRAMINE HYDROCHLORIDE, ZINC ACETATE] (C - n/a - n/a - [n/a - n/a - Transplacental]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Transplacental]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Transplacental])	<a href="#">ICSR</a>
EU-EC-10010276555	11/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Decreased appetite (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Heart rate increased (n/a - Recovering/Resolving - Other Medically Important Condition), Infant irritability (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Thirst decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010276593	11/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Faeces discoloured (n/a - Unknown - Other Medically Important Condition), Fatigue (4d - Recovered/Resolved - Other Medically Important Condition), Infant irritability (n/a - Unknown - Other Medically Important Condition), Insomnia (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

										Medically Important Condition)			
EU-EC-10010283088	11/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010283874	11/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Body temperature increased (1d - Recovered/Resolved - ), Frequent bowel movements (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010285518	11/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Cough (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - ), Nasal congestion (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Sneezing (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010286244	11/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Not Specified	Yes	Congenital musculoskeletal disorder of limbs (105d - Fatal - Results in Death, Congenital Anomaly), Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital Anomaly), Limb reduction defect (105d - Fatal - Results in Death, Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CYANOCOBALAMIN, FOLIC ACID, POTASSIUM IODIDE, POTASSIUM IODIDE] (C - Pregnancy - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010246062	07/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Chills (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010246777	07/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010254324	07/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Recovering/Resolving - Other Medically Important Condition), Ocular hyperaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Periorbital swelling (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>



										Medically Important Condition), Rhinorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Screaming (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sleep disorder (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10010230832	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010236564	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Diarrhoea (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010237300	06/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Infantile vomiting (1d - Recovered/Resolved - Other Medically Important Condition), Regurgitation (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010239957	06/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010243592	06/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Poor feeding infant (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010204391	04/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Hypersomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infant irritability (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

										Poor feeding infant (n/a - Unknown - Other Medically Important Condition),  Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010208558	04/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Epistaxis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Feeling abnormal (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010210329	04/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Hypoxic-ischaemic encephalopathy (n/a - Fatal - Results in Death),  Neonatal anoxia (n/a - Fatal - Results in Death),  Neonatal multi-organ failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010195922	01/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Abdominal pain (48h - Recovered/Resolved - ),  Diarrhoea (48h - Recovered/Resolved - ),  Infantile spitting up (48h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010197807	01/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),  Weight gain poor (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010173201	30/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Diet refusal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Poor feeding infant (n/a - Unknown - Other Medically Important Condition),  Rash (n/a - Recovering/Resolving - Other Medically Important Condition),  Urine output decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])  [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a]),  [PARACETAMOL, PARACETAMOL PH. EUR.] (C - Nasal congestion - n/a - [n/a - n/a - n/a]),  [RETINOL PALMITATE, ERGOCALCIFEROL BP, NICOTINAMIDE BP, RIBOFLAVIN BP, ASCORBIC ACID BP, THIAMINE HYDROCHLORIDE BP, PYRIDOXINE HYDROCHLORIDE BP, RETINOL PALMITATE, ERGOCALCIFEROL PH. EUR., NICOTINAMIDE BP, RIBOFLAVIN BP, ASCORBIC ACID BP, THIAMINE HYDROCHLORIDE BP, PYRIDOXINE HYDROCHLORIDE BP, RETINOL PALMITATE, THIAMINE HYDROCHLORIDE, ASCORBIC ACID, ERGOCALCIFEROL,		<a href="#">ICSR</a>

												NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - Premature baby - n/a - [n/a - n/a - n/a]),  [SODIUM FEREDATE, SODIUM FEREDATE TRIHYDRATE] (C - Premature baby - n/a - [n/a - n/a - n/a])	
EU-EC-10010160318	29/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Alopecia totalis (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010166850	29/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010171029	29/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Headache (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010171983	29/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),  Rhinorrhoea (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010148558	28/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ),  Headache (n/a - Unknown - Other Medically Important Condition),  Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	[IBUPROFEN] (C - Teething - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010152356	28/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Poor quality sleep (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010152362	28/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Ear pain (n/a - Recovering/Resolving - Other Medically Important Condition),  Nasopharyngitis (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	<a href="#">ICSR</a>

											Pain in extremity (2d - Recovered/Resolved - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Rhinorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sinus pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010153783	28/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Emotional distress (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010154987	28/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Gait disturbance (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010135247	27/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Angioedema (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010135343	27/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Exposure via breast milk (n/a - Recovering/Resolving - Other Medically Important Condition), Lethargy (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Teething - n/a - [2d - n/a - n/a])	<a href="#">ICSR</a>	
EU-EC-10010138222	27/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[PARACETAMOL] (C - Headache - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>	
EU-EC-10010142787	27/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months	Infant	Female	Yes	Pyrexia (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN]	Not reported	<a href="#">ICSR</a>	

			Professional	Area		- 2 Years				- ), Rhinitis (n/a - Recovered/Resolved - )	(S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10010143228	27/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Cough (n/a - Recovered/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Somnolence (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010144544	27/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Diarrhoea neonatal (4d - Recovered/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Infantile vomiting (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010145144	27/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Diarrhoea (3d - Recovered/Resolved - ), Exposure via breast milk (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010116922	24/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010125334	24/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

EU-EC-10010083894	21/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Diarrhoea (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010065652	20/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Hypotonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Somnolence (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010069609	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Hypersomnia (24h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Oral])	Not reported	<a href="#">ICSR</a>
EU-EC-10010069804	20/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Foetal growth restriction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [41d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010070750	20/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	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])	[FOLATE SODIUM] (C - Prenatal care - n/a - [244d - n/a - Transplacental]),  [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Transplacental]),  [VITAMINS NOS] (C - Prenatal care - n/a - [244d - n/a - Transplacental]),  [VITAMINS NOS] (C - Prenatal care - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10010073173	20/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Foetus	Not Specified	Yes	Foetal exposure during pregnancy (14d - Fatal - Results in Death),  Heart disease congenital (14d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010046212	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010047138	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Malaise (2d - Recovering/Resolving - ),  Vaccination site pain (2d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	<a href="#">ICSR</a>
EU-EC-10010047149	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (1d - Recovered/Resolved - ),  Malaise (1d - Recovered/Resolved - ),  Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-	18/09/2021	Spontaneous	Non	European	Not	0-1	Adult	Female	No	Hypoaesthesia (2d -	COMIRNATY	Not reported	<a href="#">ICSR</a>

10010047437			Healthcare Professional	Economic Area	available	Month				Recovered/Resolved - ), Paraesthesia (2d - Recovered/Resolved - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10010051087	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Feeling cold (3d - Recovered/Resolved - ), Lymphadenopathy (3d - Recovered/Resolved - ), Myalgia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010051879	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperpyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010053302	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (0d - Recovered/Resolved - ), Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010030863	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Pruritus (n/a - Not Recovered/Not Resolved - ), Skin reaction (n/a - Not Recovered/Not Resolved - ), Stomatitis (n/a - Not Recovered/Not Resolved - ), Tic (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10010037750	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Malaise (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010039817	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	Yes	Agitation (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [30d - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010039949	17/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Urticaria (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010043661	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Abdominal distension (5d - Not Recovered/Not Resolved - ), Abdominal pain (5d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010045177	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10010047378	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10010048942	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Abnormal sensation in eye (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - )	Not reported	<a href="#">ICSR</a>

											Erythema (0d - Recovered/Resolved - ), Fatigue (0d - Recovered/Resolved - ), Feeling hot (0d - Recovered/Resolved - ), Lacrimation increased (0d - Recovered/Resolved - )	- n/a - [n/a - n/a - n/a]		
EU-EC-10010049012	17/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Injection site swelling (n/a - Unknown - ), Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10010014650	15/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009989870	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Anencephaly (n/a - Fatal - Results in Death, Congenital Anomaly), Maternal exposure before pregnancy (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [78d - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009972634	12/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Chills (7d - Recovered/Resolved - ), Fatigue (7d - Recovered/Resolved - ), Insomnia (7d - Recovered/Resolved - ), Nausea (7d - Recovered/Resolved - ), Pyrexia (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009968984	11/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Headache (7d - Recovered/Resolved - ), Lymphadenopathy (7d - Recovered/Resolved - ), Malaise (7d - Recovered/Resolved - ), Musculoskeletal pain (7d - Recovered/Resolved - ), Vaccination site pain (7d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	



										Recovered/Resolved - )			
EU-EC-10009969068	11/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Fatigue (7d - Recovered/Resolved - ), Musculoskeletal pain (7d - Recovered/Resolved - ), Vaccination site pain (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009966821	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Vomiting projectile (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009954883	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009930956	08/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Restlessness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009939699	08/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Back pain (n/a - Recovering/Resolving - ), Headache (1d - Recovering/Resolving - ), Hot flush (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC-10009926541	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Female	Yes	Foetal growth restriction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [25d - .3mL - Transplacental])	Not reported	<a href="#">ICSR</a>
EU-EC-10009926552	07/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Female	Yes	Intestinal dilatation (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [38d - .3mL - Transplacental])	Not reported	<a href="#">ICSR</a>
EU-EC-10009907996	06/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Neonatal respiratory distress (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - Transmammary]), [NIFEDIPINE] (C - Hypertension - n/a - [n/a - n/a - Transmammary])	<a href="#">ICSR</a>
EU-EC-10009912425	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Fungal infection (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009912498	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Pyrexia (1d - Recovered/Resolved - ), Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009894546	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months	Not Specified	Male	Yes	Irritability (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<a href="#">ICSR</a>

						- 2 Years					immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10009884487	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Recovering/Resolving - Life Threatening),  Febrile convulsion (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009893432	03/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Rash (2d - Recovered/Resolved - Other Medically Important Condition),  Urticaria (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009867557	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	Yes	Body temperature increased (n/a - Recovered/Resolved - ),  Cough (n/a - Recovered/Resolved - ),  Exposure via breast milk (n/a - Recovered/Resolved - ),  Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),  Rhinorrhoea (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009868149	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adolescent	Male	No	Lymphadenopathy (2wk - Recovered/Resolved - ),  Pain in extremity (2wk - Recovered/Resolved - )	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009877264	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Discomfort (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Dizziness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Facial pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Headache (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Mastication disorder (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Neuralgia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Swelling face (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Vision blurred (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>

											Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10009877298	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adolescent	Male	No	Partial seizures (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009859637	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Not Specified	No	Pyrexia (24h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009860422	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009864436	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009849028	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Crying (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Rhinorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009849038	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Asthenia (n/a - Not Recovered/Not Resolved - ), Discomfort (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009810713	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[PARACETAMOL, PARACETAMOL PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>	
EU-EC-10009815529	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Crying (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - ), Infantile vomiting (n/a - Unknown - Other Medically Important Condition), Poor feeding infant (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Poor feeding infant (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009815848	27/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Rash morbilliform (5d -	COMIRNATY [TOZINAMERAN]	Not reported	<a href="#">ICSR</a>	

			Professional	Area							Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])		
EU-EC-10009794367	26/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Erythema (n/a - Unknown - ), Rash (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009795961	26/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009800095	26/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Sleep disorder (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009800892	26/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Irritability (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009800948	26/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009801993	26/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009802441	26/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Sleep disorder (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Oral])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009784890	25/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	Yes	Agitation (n/a - Recovering/Resolving - ), Crying (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009792497	25/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009770537	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009776683	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Malaise (n/a - Recovered/Resolved - ), Vomiting (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>	
EU-EC-10009761163	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Dehydration (2d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (2d - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	

											Condition), Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10009762070	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Cough (n/a - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Respiration abnormal (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009764568	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Gastritis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	<a href="#">ICSR</a>	
EU-EC-10009752665	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009752770	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Constipation (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009752782	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009740844	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Vomiting (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009745550	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Dehydration (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (48h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Exposure via breast milk (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (48h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009748646	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Apgar score low (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Foetal distress syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Transplacental])	Not reported	<a href="#">ICSR</a>	

										Condition), Neonatal respiratory failure (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis neonatal (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10009734955	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009738127	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Dysphonia (n/a - Not Recovered/Not Resolved - Disabling), Exposure via breast milk (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009738722	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009708538	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009691077	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Crying (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - ), Restlessness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009693256	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Crying (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009696200	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Diarrhoea (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009701047	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Weight increased (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009687054	14/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Phlebitis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009675834	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure during pregnancy (n/a - Unknown - ), Pyrexia (n/a - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - )	Not reported	<a href="#">ICSR</a>

										Recovered/Resolved - ), Rhinorrhoea (n/a - Recovered/Resolved - ), Sleep disorder (n/a - Recovered/Resolved - ), Sneezing (n/a - Recovered/Resolved - )	n/a - Transmammary])		
EU-EC-10009682532	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009683088	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Dark circles under eyes (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Insomnia (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009684875	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	[TOLFENAMIC ACID] (C - Migraine - n/a - [n/a - n/a - Oral])	<a href="#">ICSR</a>
EU-EC-10009661118	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Pyrexia (n/a - Recovering/Resolving - ), Vomiting projectile (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009669520	12/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Hypoglycaemia neonatal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypothermia neonatal (n/a - Unknown - Caused/Prolonged Hospitalisation), Infantile apnoea (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	<a href="#">ICSR</a>
EU-EC-10009669972	12/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009651855	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Body temperature increased (2d - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - ), Malaise (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009653067	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Hypotonia neonatal (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - )	[LAMOTRIGINE] (C - Epilepsy - Dose not changed - [n/a - 100mg - Oral]),	<a href="#">ICSR</a>

											Hypoxic-ischaemic encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Small for dates baby (n/a - Unknown - Caused/Prolonged Hospitalisation)	[n/a - .3mL - Intramuscular]) [LEVOTHYROXINE (C - Hypothyroidism - Dose not changed - [n/a - 50ug - Oral])]		
EU-EC-10009659470	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009660183	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Drug ineffective (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009639260	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	Limb discomfort (16386d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009645938	10/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009626189	09/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Influenza (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown - ), Urinary incontinence (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009626381	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009627814	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Abnormal behaviour (n/a - Unknown - ), Discomfort (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - ), Restlessness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009630866	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - ), Nasal congestion (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rhinoorrhoea (n/a - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	



										Unknown - ), Suspected COVID-19 (n/a - Unknown - )			
EU-EC-10009631536	09/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),  Premature baby (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR])	Not reported	<a href="#">ICSR</a>
EU-EC-10009633389	09/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Product administered to patient of inappropriate age (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009614110	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Crying (n/a - Recovering/Resolving - ),  Exposure via breast milk (n/a - Unknown - ),  Insomnia (n/a - Recovering/Resolving - ),  Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009614444	06/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Feeling abnormal (n/a - Unknown - Other Medically Important Condition),  Infantile vomiting (n/a - Recovering/Resolving - Other Medically Important Condition),  Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Mucous stools (n/a - Unknown - Other Medically Important Condition),  Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Poor feeding infant (n/a - Unknown - Other Medically Important Condition),  Urine output decreased (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>

											Medically Important Condition)			
EU-EC-10009617434	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009617435	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - ), Rash (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009618392	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - ), Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009596230	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved - ), Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009598587	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (1d - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Vomiting (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009599054	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009599069	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009604273	05/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Inguinal hernia (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 20mg - Transplacental]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [LORATADINE] (C - n/a - n/a - [n/a - 10mg - Transplacental]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Gestational diabetes - n/a - [n/a - 750mg - Transplacental]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - Transplacental]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Transplacental])	<a href="#">ICSR</a>		
EU-EC-10009590574	04/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Bronchitis (11d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	

EU-EC-10009569908	03/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Insomnia (n/a - Unknown - ), Irritability (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009558979	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Body temperature fluctuation (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Premature baby (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009561299	02/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (0d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009539219	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Elderly	Male	No	Cough (0d - Recovered/Resolved - ), Larynx irritation (0d - Recovered/Resolved - ), Local reaction (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009539239	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	Influenza (2d - Recovered/Resolved - ), Oropharyngeal pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009539256	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Circulatory collapse (3d - Recovered/Resolved - ), Influenza like illness (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009543465	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Infant irritability (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009543469	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - ), Sleep disorder (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009549501	30/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Axillary pain (n/a - Recovering/Resolving - ), Headache (2d - Recovered/Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Oral herpes (n/a - Not Recovered/Not Resolved - ), Pyrexia (2d - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - )	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[VALSARTAN, AMLODIPINE BESILATE] (C - Hypertension - n/a - [9mo - 5mg - Oral]), [VINPOCETINE] (C - Cerebrovascular disorder - n/a - [n/a - 10mg - Oral])	<a href="#">ICSR</a>
EU-EC-10009529762	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (72h - Recovered/Resolved - ), Headache (72h - Recovered/Resolved - ), Lymphadenopathy (72h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>

										- ), Nausea (72h - Recovered/Resolved - ), Pyrexia (72h - Recovered/Resolved - )			
EU-EC-10009534678	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009535417	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009535443	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009515400	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Headache (n/a - Not Recovered/Not Resolved - ), Limb discomfort (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009517206	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (0d - Recovered/Resolved - ), Influenza (0d - Recovered/Resolved - ), Limb discomfort (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009517693	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site pain (0d - Recovered/Resolved - ), Pain in extremity (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009517823	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Erythema (n/a - Recovering/Resolving - ), Vaccination site reaction (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009517897	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Injection site movement impairment (0d - Recovering/Resolving - ), Injection site pain (0d - Recovering/Resolving - ), Pain in extremity (0d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	<a href="#">ICSR</a>
EU-EC-10009518248	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (0d - Recovered/Resolved - ), Fatigue (0d - Recovered/Resolved - ), Headache (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-	28/07/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	Fatigue (3d -	COMIRNATY	Not reported	<a href="#">ICSR</a>

10009518276			Healthcare Professional	Economic Area	available	Months - 2 Years					Recovered/Resolved - ), Hypotonia (3d - Recovered/Resolved - ), Influenza (1d - Recovered/Resolved - ), Influenza like illness (1d - Recovered/Resolved - ), Injection site pain (31d - Not Recovered/Not Resolved - ), Injection site pain (3d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ), Myalgia (31d - Not Recovered/Not Resolved - ), Pain in extremity (1d - Recovered/Resolved - ), Pain in extremity (3d - Recovered/Resolved - ), Vaccination site hypersensitivity (1d - Recovered/Resolved - ), Vaccination site hypersensitivity (3d - Recovered/Resolved - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])		
EU-EC-10009518438	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Influenza like illness (1d - Recovering/Resolving - ), Sleep disorder (1d - Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009520401	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009522681	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Epistaxis (1d - Recovered/Resolved - ), Epistaxis (1d - Recovering/Resolving - ), Influenza like illness (1d - Recovered/Resolved - ), Injection site pain (1d - Recovered/Resolved - ), Injection site pain (1d - Recovering/Resolving - ), Nasopharyngitis (1d - Recovered/Resolved - ), Nasopharyngitis (1d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	<a href="#">ICSR</a>	

											- ), Oropharyngeal pain (1d - Recovered/Resolved - ), Oropharyngeal pain (1d - Recovering/Resolving - ), Sleep disorder (1d - Recovered/Resolved - ), Sleep disorder (1d - Recovering/Resolving - ), Sneezing (1d - Recovered/Resolved - ), Sneezing (1d - Recovering/Resolving - ), Vision blurred (1d - Recovered/Resolved - ), Vision blurred (1d - Recovering/Resolving - )			
EU-EC-10009495876	27/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009496347	27/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Crying (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009478995	26/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009486242	26/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Dermatitis diaper (6d - Recovered/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009467734	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	No	Faeces pale (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009451312	22/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Diarrhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (3min - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009454119	22/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<a href="#">ICSR</a>	

											Rash erythematous (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Unknown - Other Medically Important Condition)	n/a - Transmammary])		
EU-EC-10009435335	21/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Growth failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - n/a])	<a href="#">ICSR</a>	
EU-EC-10009435494	21/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009421923	20/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Crying (n/a - Recovered/Resolved - ), Nervousness (n/a - Recovered/Resolved - ), Restlessness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009431105	20/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), Crying (n/a - Recovering/Resolving - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infant irritability (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Restlessness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009399654	18/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Epistaxis (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - ), Eye haemorrhage (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009383924	16/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009384608	16/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Unknown - Caused/Prolonged)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<a href="#">ICSR</a>	

						- 2 Years					Hospitalisation), Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation)	immunisation - Not applicable - [1d - n/a - Transmammary])		
EU-EC- 10009384629	16/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes		Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation),  Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC- 10009390346	16/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes		Exposure via breast milk (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition),  Haematochezia (34d - Recovered/Resolved - Congenital Anomaly, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC- 10009370932	15/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes		Diarrhoea neonatal (n/a - Unknown - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Infantile vomiting (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	<a href="#">ICSR</a>
EU-EC- 10009377814	15/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes		Premature baby (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC- 10009361072	14/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes		Exposure via breast milk (1d - Recovered/Resolved - Other Medically Important Condition),  Illness (0d - Recovered/Resolved - Other Medically Important Condition),  Infantile vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC- 10009349807	13/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes		Exposure via breast milk (n/a - Unknown - ),  Poor feeding infant (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC- 10009339701	12/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No		Exposure via breast milk (n/a - Unknown - ),  Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC- 10009321662	09/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No		Chills (1d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC- 10009303737	08/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes		Body temperature increased (n/a - Recovering/Resolving - ),  Cough (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>



											Crying (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Unknown - ), Listless (n/a - Recovering/Resolving - ), Upper respiratory tract infection (n/a - Recovering/Resolving - )			
EU-EC-10009304693	08/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (0d - Unknown - ), Vomiting (0d - 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])	<a href="#">ICSR</a>	
EU-EC-10009304702	08/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009305138	08/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Exposure via breast milk (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009293497	07/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Elderly	Male	No	Vaccination failure (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009282163	06/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009256589	05/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10009256702	05/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Faeces discoloured (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	

										Medically Important Condition)			
EU-EC-10009258639	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Anosmia (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Lymphadenopathy (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009237030	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Constipation (6d - Recovering/Resolving - Other Medically Important Condition), Exposure via breast milk (n/a - Recovering/Resolving - Other Medically Important Condition), Nasopharyngitis (6d - Recovering/Resolving - Other Medically Important Condition), Pyrexia (6d - Recovering/Resolving - Other Medically Important Condition), Weight decreased (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009237717	02/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009239701	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Fatigue (24h - Recovered/Resolved - ), Influenza like illness (24h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009229804	01/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009204732	30/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Pyrexia (13d - Recovered/Resolved - Disabling), Vomiting (13d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Transmammary])	[LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - Transmammary]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - Transmammary]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Transmammary])	<a href="#">ICSR</a>
EU-EC-10009208487	30/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>

										Listless (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Recovered/Resolved - )			
EU-EC-10009188382	29/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Diarrhoea (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009192995	29/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009168851	28/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009181222	28/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Male	Yes	Crying (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Restlessness (n/a - Not Recovered/Not Resolved - ), Sleep disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009143183	25/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Rash (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009144709	25/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arthralgia (4d - Recovered/Resolved - ), Asthenia (2d - Recovered/Resolved - ), Headache (4d - Recovered/Resolved - ), Myalgia (4d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [4d - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009152789	25/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Dysgeusia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	<a href="#">ICSR</a>
EU-EC-10009131725	24/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (3d - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009135091	24/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Abdominal discomfort (2d - Recovered/Resolved - ), Arthralgia (2d - Recovered/Resolved - ), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - n/a - [1d - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Autoimmune	<a href="#">ICSR</a>

										(2d - Recovered/Resolved - ), Dizziness (2d - Recovered/Resolved - ), Fatigue (6d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Lymphadenopathy (9d - Recovered/Resolved - ), Pain in extremity (3d - Recovered/Resolved - ), Pain in extremity (5d - Recovered/Resolved - )		hypothyroidism - n/a - [n/a - n/a - n/a]	
EU-EC-10009098964	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - ), Lymph node pain (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (17h - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009100614	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Muscular weakness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009101906	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Breast pain (3d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009104292	22/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10009089559	21/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10009093553	21/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - ), Rhinorrhoea (n/a - Recovered/Resolved - ), Upper respiratory tract infection (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10009060463	18/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Crying (n/a - Unknown - Other Medically Important Condition), Mood swings (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	<a href="#">ICSR</a>
EU-EC-10009063293	18/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Pruritus (2wk - Recovered/Resolved - )	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE)	[NEBIVOLOL] (C - n/a - n/a - [n/a - 5mg - Oral])	<a href="#">ICSR</a>



				Economic Area		- 2 Years				Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infant irritability (n/a - Unknown - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - Transmammary])		
EU-EC-10008969551	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Agitation (5d - Recovered/Resolved - ), Diarrhoea (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008969744	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Gastrointestinal pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008971309	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (4d - Recovering/Resolving - ), Dizziness (4d - Recovering/Resolving - ), Headache (4d - Recovering/Resolving - ), Nausea (4d - Recovering/Resolving - ), Vomiting (4d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10008973224	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Rash (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10008922721	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	No	Diarrhoea neonatal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Exposure via breast milk (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Infantile vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash erythematous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10008931182	07/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Dermatitis allergic (n/a - Unknown - ), Rash (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10008913478	05/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Skin discolouration (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008866751	02/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008872929	02/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Crying (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Listless (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	<a href="#">ICSR</a>

										Recovered/Not Resolved - ), Pain (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC-10008850480	01/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - ), Overfeeding of infant (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10008854541	01/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	Yes	Crying (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Rhinorrhoea (n/a - Unknown - )	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008822508	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])	<a href="#">ICSR</a>
EU-EC-10008801243	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008801915	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008803586	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Diarrhoea (6d - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008806516	27/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008776925	26/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Pain (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10008788314	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10008788572	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Decreased appetite (1d - Recovered/Resolved - ), Irritability (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10008771729	25/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months	Elderly	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	<a href="#">ICSR</a>

						- 2 Years					Influenza (n/a - Not Recovered/Not Resolved - ),  Injection site pain (1d - Recovered/Resolved - )	- n/a - [n/a - n/a - Intramuscular]		
EU-EC-10008772057	25/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (n/a - Recovered/Resolved - ),  Headache (n/a - Recovered/Resolved - ),  Hyperhidrosis (n/a - Recovered/Resolved - ),  Insomnia (n/a - Recovered/Resolved - ),  Myalgia (n/a - Recovered/Resolved - ),  Nausea (n/a - Recovered/Resolved - ),  Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008774822	25/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008762223	24/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008732339	21/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (n/a - Recovered/Resolved - ),  Dry mouth (n/a - Recovered/Resolved - ),  Headache (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008733276	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ),  Screaming (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008721135	20/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza like illness (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008672275	17/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Lip disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),  Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),  Transient ischaemic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008634274	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months	Not Specified	Female	No	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<a href="#">ICSR</a>	



						- 2 Years					Poor quality sleep (n/a - Unknown - )	immunisation - Not applicable - [n/a - n/a - Transmammary]		
EU-EC-10008579795	08/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Asthenia (6d - Recovering/Resolving - ), Headache (6d - Recovered/Resolved - ), Influenza like illness (6d - Recovered/Resolved - ), Pyrexia (6d - Recovered/Resolved - ), Tremor (6d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a])	TECFIDERA 240 MG [DIMETHYL FUMARATE] (C - Multiple sclerosis - n/a - [n/a - 480mg - Oral])	<a href="#">ICSR</a>	
EU-EC-10008572439	07/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Influenza like illness (3d - Recovered/Resolved - ), Limb discomfort (3d - Recovered/Resolved - ), Nausea (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008554384	06/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (1d - Recovered/Resolved - ), Injection site pain (1d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ), Myalgia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008522917	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Decreased appetite (3d - Recovered/Resolved - ), Irritability (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008502098	01/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Deep vein thrombosis (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (1d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008478704	29/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (5d - Recovered/Resolved - ), Rash (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008449790	27/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Recovered/Resolved - ), Pyrexia (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008416301	23/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Cystitis (n/a - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NON SPECIFIED ANTICOAGULANS [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]),	<a href="#">ICSR</a>	

											Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Palpitations (8h - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - )	applicable - [n/a - 1{DF} - n/a]	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10008386439	21/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Fever neonatal (3d - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - ), Rash (1wk - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Other])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008388576	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	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	<a href="#">ICSR</a>	
EU-EC-10008368804	20/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Chills (n/a - Recovering/Resolving - ), Decreased appetite (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Injection site pain (n/a - Recovering/Resolving - ), Injection site swelling (n/a - Recovering/Resolving - ), Lymphadenopathy (2d - Recovered/Resolved - ), Lymphadenopathy (n/a - Recovering/Resolving - ), Myalgia (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ), Vaccination site joint movement impairment (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - )	<a href="#">ICSR</a>	

											Vaccination site pain (2d - Recovered/Resolved -)			
EU-EC-10008373766	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Action tremor (n/a - Recovering/Resolving -), Blood pressure systolic increased (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Heart rate increased (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008355561	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Cough (n/a - Recovered/Resolved - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Infant irritability (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition), Wheezing (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008356645	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Cyanosis (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), KEPPRA [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C -		<a href="#">ICSR</a>	

												n/a - n/a - [n/a - n/a - n/a]	
EU-EC-10008323550	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Recovering/Resolving - Other Medically Important Condition), Fever neonatal (n/a - Recovering/Resolving - Other Medically Important Condition), Rash neonatal (n/a - Recovering/Resolving - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10008304699	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved - Other Medically Important Condition), Viral infection (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10008308143	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Aphthous ulcer (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10008274942	12/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Ear infection (n/a - Recovering/Resolving - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown - ), Nasopharyngitis (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rhinorrhoea (7d - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 137ug - Transmammary]), [SULFASALAZINE] (C - Arthritis - n/a - [n/a - 1000mg - Transmammary])	<a href="#">ICSR</a>
EU-EC-10008282818	12/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Recovered/Resolved - ), Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition), Wheezing (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10008250035	09/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	No	Feeling hot (3d - Recovering/Resolving - ), Headache (3d - Recovering/Resolving - ), Influenza (3d - Recovering/Resolving - ), Lymphadenitis (3d - Recovering/Resolving - ), Myalgia (3d - Recovering/Resolving - ), Somnolence (3d - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>

											Recovering/Resolving - )			
EU-EC-10008234417	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Asthenia (n/a - Unknown - ), Chills (n/a - Unknown - ), Dysgeusia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008221718	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Crying (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008177763	03/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008165759	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Disabling), Neuralgia (n/a - Unknown - Disabling)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008150280	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008093791	27/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Nervousness (5d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Oral])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008093826	27/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (3d - Recovered/Resolved - Other Medically Important Condition), Insomnia (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Oral])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008083321	26/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arthralgia (2d - Recovered/Resolved - ), Asthenia (2d - Recovered/Resolved - ), Fatigue (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Lymphadenopathy (2d - Recovered/Resolved - ), Lymphadenopathy (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC-10008042963	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<a href="#">ICSR</a>	

											Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - Oral])	
EU-EC-10008004395	20/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Febrile convulsion (n/a - Recovered/Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10007966031	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Dizziness (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - ), Hypertension (3d - Recovered/Resolved - ), Tinnitus (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007971748	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Not Specified	No	Fatigue (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007945446	16/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthma (n/a - Unknown - ), Respiratory distress (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007884848	10/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Pain in extremity (0d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007857596	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Infant irritability (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007859661	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10007866820	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Fatigue (18d - Not Recovered/Not Resolved - ), Feeling cold (18d - Not Recovered/Not Resolved - ), Headache (18d - Not Recovered/Not Resolved - ), Muscle twitching (18d - Not Recovered/Not Resolved - ), Somnolence (18d - Not Recovered/Not Resolved - ), Vaccination site pain (18d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007866881	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Headache (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007852125	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN]	Not reported	<a href="#">ICSR</a>


			Professional	Area							- ), Muscular weakness (1d - Recovered/Resolved - )	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10007852266	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (n/a - Not Recovered/Not Resolved - ),  Dizziness (n/a - Not Recovered/Not Resolved - ),  Headache (n/a - Not Recovered/Not Resolved - ),  Pain in extremity (n/a - Not Recovered/Not Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC- 10007852282	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ),  Dyspnoea (n/a - Not Recovered/Not Resolved - ),  Peripheral vascular disorder (n/a - Not Recovered/Not Resolved - ),  Respiratory distress (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC- 10007852724	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Abdominal pain (2d - Recovered/Resolved - ),  Headache (2d - Recovered/Resolved - ),  Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC- 10007770028	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Hypoxia (n/a - Recovering/Resolving - Other Medically Important Condition),  Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>	
EU-EC- 10007781698	03/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Infant irritability (n/a - Unknown - Other Medically Important Condition),  Skin exfoliation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>	
EU-EC- 10007771100	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Exposure via breast milk (3d - Recovered/Resolved - Other Medically Important Condition),  Faeces discoloured (2d - Recovered/Resolved - Other Medically Important Condition),  Headache (3d - Recovered/Resolved - Other Medically Important Condition),  Infant irritability (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Transmammary])	Not reported	<a href="#">ICSR</a>	

										- Other Medically Important Condition), Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007664316	19/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (1d - Unknown - ), Listless (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10007631251	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Dry mouth (n/a - Unknown - ), Hypoaesthesia oral (1d - Recovered/Resolved - )	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10007554790	09/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Back pain (n/a - Unknown - Disabling, Other Medically Important Condition), Chest discomfort (n/a - Unknown - Disabling, Other Medically Important Condition), Cough (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Fatigue (n/a - Unknown - Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Musculoskeletal pain (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Nasal odour (4d - Recovered/Resolved - Disabling, Other Medically Important Condition), Pain in extremity (2d - Recovered/Resolved - Disabling, Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10007531350	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (24h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10007513447	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	<a href="#">ICSR</a>
EU-EC-10007456071	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Syncope (0d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-	25/01/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	Back pain (5d - Not	COMIRNATY	Not reported	<a href="#">ICSR</a>



10007420806			Healthcare Professional	Economic Area	available	Months - 2 Years				Recovered/Not Resolved - ), Disturbance in attention (3d - Not Recovered/Not Resolved - ), Headache (5d - Recovering/Resolving - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous])		
EU-EC-10007376233	19/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Eye pain (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	<a href="#">ICSR</a>
EU-EC-10007364616	18/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Lymphadenopathy (1d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<a href="#">ICSR</a>
EU-EC-10007346597	14/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Dizziness (0d - Recovered/Resolved - ), Fatigue (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007346678	14/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007348836	14/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Nausea (0d - Recovered/Resolved - ), Vomiting (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007348888	14/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	Asthenia (0d - Recovered/Resolved - ), Headache (0d - Recovered/Resolved - ), Injection site pain (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007349128	14/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Dizziness (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007326285	11/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	No	Fatigue (4d - Recovering/Resolving - ), Headache (4d - Recovering/Resolving - ), Therapeutic product ineffective (4d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ARTICAINE HYDROCHLORIDE, EPINEPHRINE] (C - Anaesthesia - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	<a href="#">ICSR</a>
EU-EC-10007329584	11/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Blood pressure increased (0d - Not Recovered/Not Resolved - ), Peripheral vascular disorder (0d - Not Recovered/Not Resolved - ), Vaccination site reaction (0d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>

EU-EC-10007324126	09/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Vomiting (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007319258	08/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Erythema (0d - Recovered/Resolved - ), Skin discolouration (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007298862	05/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Headache (2d - Recovered/Resolved - ), Pain in extremity (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007291612	04/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Abnormal faeces (0d - Recovered/Resolved - ), Chills (2d - Recovering/Resolving - ), Dizziness (2d - Not Recovered/Not Resolved - ), Erythema (2d - Not Recovered/Not Resolved - ), Fatigue (2d - Not Recovered/Not Resolved - ), Nausea (2d - Not Recovered/Not Resolved - ), Pain in extremity (2d - Not Recovered/Not Resolved - ), Vaccination site reaction (2d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007293339	04/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (0d - Recovering/Resolving - ), Diarrhoea (0d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007293590	04/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Myalgia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>
EU-EC-10007293591	04/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arthralgia (3d - Recovering/Resolving - ), Myalgia (3d - Recovering/Resolving - ), Pyrexia (3d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<a href="#">ICSR</a>

 Rows 1 - 480 (All Rows)

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