## **Line Listing Report** Time run: 30/11/2022 03:05:44

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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Pyrexia (n/a - Unknown - Other Medically Important Condition)	Transmammary])		
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Cold sweat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Transmammary])		
										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)			
EU-EC- 100111119319	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 1{DF} - n/a])	
										COVID-19 immunisation (n/a - Unknown - Caused/Prolonged Hospitalisation),	Intramuscular]), VAXZEVRIA [COVID-19 VACCINE		
										Foetal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation),	ASTRAZENECA (CHADOX1 NCOV- 19)] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL -		
										Thrombocytosis (2mo - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Intramuscular])		
EU-EC- 10011126489	30/12/2021	Spontaneous	Healthcare	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	ICSR

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EU-EC- 10011103857	29/12/2021	Spontaneous	Non Healthcare Professional	Economic	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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011111528	29/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Condition)  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	ICSR
EU-EC- 10011093644	28/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	- )  Exposure via breast milk (n/a - nilk (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	ICSR
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]) - Intramuscular])	
EU-EC- 10011099764	28/12/2021	Spontaneous	Healthcare	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	ICSR
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	ICSR
EU-EC- 10011100784	28/12/2021	Spontaneous	Healthcare	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	ICSR
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	ICSR
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	<u>ICSR</u>

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				Area		- 2 Years				Suspected COVID-19	(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]	Not reported	ICSR
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	ICSR
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	ICSR
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
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	ICSR
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	ICSR
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	ICSR
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	ICSR
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])	ICSR
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	ICSR
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	ICSR

										Medically Important			
EU-EC- 10010970281	15/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Condition)  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	ICSR
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 -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
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])	ICSR
EU-EC- 10010955230		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	- 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 - n/a])	ICSR
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),  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	ICSR
EU-EC- 10010940528	13/12/2021	Spontaneous	Healthcare	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	ICSR
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	ICSR
EU-EC- 10010942668	13/12/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	2 Months	Not Specified	Not Specified	Yes	Exposure via breast milk (0d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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				Area		Years				Important Condition),	applicable - [1d - n/a - Transmammary])		
										Somnolence (0d - Recovered/Resolved - Other Medically Important Condition)	,,,,,		
EU-EC- 1.0010942766	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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Somnolence (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 1.0010932225	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])	CELLCEPT [MYCOPHENOLATE MOFETIL] (C - n/a - n/a - [n/a - 2000mg - Oral]),	ICS
												[CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, COLECALCIFEROL CONCENTRATE (OILY FORM)] (C - n/a - n/a - [n/a - 20000[iU] - Oral]),	
												[PREDNISOLONE] (C - n/a - n/a - [n/a - 5mg - Oral]), [RAMIPRIL] (C - n/a	
												- n/a - [n/a - 2.5mg - Oral])	
EU-EC- 10010922347	10/12/2021	Spontaneous	Healthcare	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	ICS
U-EC- 0010927361	10/12/2021	Spontaneous	Healthcare	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		Not reported	ICS
EU-EC- 1.0010928705	10/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Important Condition) Abdominal pain (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	ICS
										- ), Pyrexia (n/a - Recovering/Resolving - ),	,,,,		
										Vomiting (n/a - Recovering/Resolving - )			
U-EC- 0010906300	09/12/2021	Spontaneous	Healthcare	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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										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			5.

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										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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[CYAMEMAZINE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
			Trocessorial	71100						Lymphadenopathy (2d - Recovered/Resolved -),	immunisation - Not applicable - [1d - .5mL - Intramuscular])	[LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Rhinorrhoea (2d - Recovered/Resolved - )		[PANCREAS POWDER FROM PORCINE, PANCREATIN] (C - n/a - n/a - [n/a - n/a - n/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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Malaise (3d - Recovered/Resolved - ),	Unknown - [n/a - 1{DF} - Transmammary])		
										Pyrexia (3d - Recovered/Resolved -), Sleep disorder (3d -			
										Recovered/Resolved - ),  Vomiting (3d -			
EU EC	07/42/2024			-						Recovered/Resolved	COMMENSATION		1000
EU-EC- 10010877909	07/12/2021	Spontaneous	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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										milk (n/a - Not Recovered/Not Resolved - ),	- [iiya - iiya - iiya])		
										Faeces discoloured (n/a - Not Recovered/Not Resolved - )			
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])	ICSR
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
										Insomnia (n/a - Unknown - Other Medically Important Condition),	Transmammary])		
										Nasal congestion (n/a - Unknown - Other Medically Important Condition),			
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),			
										Ocular hyperaemia (n/a - Not Recovered/Not			

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										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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovering/Resolving - )			
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	ICSR
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - Transmammary])		
										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)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Hypersensitivity (n/a	Transmammary])		
										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010835150	02/12/2021	Spontaneous	Healthcare	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	ICSR

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										(n/a - Unknown - ), Infant irritability (n/a	.3mL - Transmammary])		
										- Unknown - ), Oral fungal infection			
										(n/a - Unknown - ), Tongue fungal			
EU-EC-	30/11/2021	Spontaneous	Healthcare	European	Not	2	Adult	Female	No	infection (n/a - Unknown - ) Derealisation (n/a -	COMIRNATY	Not reported	ICSR
10010800948			Professional	Economic Area	available	Months - 2 Years				Recovering/Resolving - ), Paraesthesia (n/a - Recovering/Resolving - )	(S - COVID-19 immunisation - Not applicable - [n/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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Musculoskeletal stiffness (1h - Recovered/Resolved	1{DF} - n/a])		
EU-EC- 10010800967	30/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2	Adult	Female	No	- )   Headache (n/a -   Recovering/Resolving  - ),	(S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
						Years				Nausea (n/a - Recovering/Resolving - )	immunisation - Not applicable - [n/a - 1{DF} - 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])	
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Myalgia (n/a - Recovering/Resolving -), Pyrexia (n/a - Not	applicable - [n/a - 1{DF} - n/a])		
EU-EC-	30/11/2021	Spontaneous	Non	European	Not	0-1	Adult	Male	No	Recovered/Not Resolved - ) Chills (n/a - Not	COMIRNATY	Not reported	ICSR
10010800987	30/11/2021	Spontaneous	Healthcare Professional	Economic Area	available	Month	Addic	riale	No	Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSK
										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 - )			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ),			
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )			
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved - ),  Constipation (n/a - Not Recovered/Not	1{DF} - n/a])		
										Resolved - ), Fatigue (n/a - Not Recovered/Not			
										Resolved - ), Headache (n/a -			
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										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	Healthcare		Not available	2 Months - 2	Adult	Female	No	Amenorrhoea (1mo - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[PANTOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
						Years				Fatigue (n/a - Recovering/Resolving - )	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010801798	30/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[CITALOPRAM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
						rears				Chills (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										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 - )			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										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 - )			
EU-EC- 10010801816	30/11/2021	Spontaneous	Non Healthcare Professional		Not available	2 Months - 2 Years	Adult	Male	No	Arthralgia (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
						1 22.0				Chills (n/a - Recovering/Resolving - ),	applicable - [n/a -		
										Fatigue (n/a - Recovering/Resolving - ),			
										Headache (0d - Recovered/Resolved - ),			
										Malaise (0d - Recovered/Resolved -),			

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										Myalgia (n/a - Recovering/Resolving - ),			
										Pyrexia (0d - Recovered/Resolved			
EU-EC- 10010801819	30/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adult	Female	No	Acne (n/a - Recovering/Resolving - ), Back pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Recovering/Resolving - ), Breast tenderness (n/a -			
										Recovering/Resolving - ), Menstruation delayed			
EU-EC-	20/11/2021	Spontaneous	Non	F	Nah	2	Adult	Female	Na	(4d - Recovering/Resolving - ) Abdominal	COMUDALITY	Not vorested	Tech
10010802609	30/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	Months - 2 Years	Adult	remaie	No	discomfort (n/a - Recovering/Resolving - ),	immunisation - Not applicable - [n/a -	Not reported	ICSF
										Abdominal distension (n/a - Recovering/Resolving -),			
										Amenorrhoea (35d - Recovered/Resolved - ),			
										Fatigue (35d - Recovered/Resolved - ),			
	201112001									Menstruation irregular (35d - Recovered/Resolved - )			
EU-EC- 10010802619	30/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adult	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved - ), Headache (n/a - Not	1{DF} - n/a])		
										Recovered/Not Resolved - ), Malaise (n/a - Not			
										Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	30/11/2021	Spontaneous	Non	European	Not	2	Adult	Male	No	Nausea (0d - Recovered/Resolved - ) Arthralgia (n/a - Not	COMIRNATY	Not reported	ICSR
10010802623	, ,	'	Healthcare	Economic Area	available	Months - 2 Years				Recovered/Not Resolved - ), Chills (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	'	
										Recovered/Not Resolved - ), Headache (n/a - Not	1{DF} - n/a])		
										Recovered/Not Resolved - ), Malaise (n/a - Not			
EU-EC-	30/11/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	Recovered/Not Resolved - ) Chills (2d -	COMIRNATY	NOT AVAILABLE (C -	ICSR
10010802626			Healthcare Professional	Economic Area	available	Months - 2 Years				Recovered/Resolved -), Diarrhoea (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - Dose not changed - [n/a - n/a - n/a]), [LITHIUM	
										Resolved - ), Fatigue (n/a - Not Recovered/Not	- (Di y = 190])	CARBONATE] (C - n/a - Dose not changed - [n/a - n/a - n/a])	
										Resolved - ), Headache (2d - Recovered/Resolved - ),			
										Injection site inflammation (2d - Recovered/Resolved			
ne://dan.en	a eurona	 .eu/analytic:	 s/saw dll26	 <del>}</del> 0	l	I		l		-),	l		10/6

								. LING L					
										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),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
										Migraine (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	J		
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/a3mL - n/a])	Not reported	ICSR
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Malaise (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - Transmammary])		
										Pyrexia (n/a - Recovering/Resolving - )			
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 -	Not reported	ICSR
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 - ),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[IBUPROFEN] (C - n/a - n/a - [n/a - n/a - Transmammary]),	ICSR
										Malaise (n/a - Recovered/Resolved - ),	applicable - [n/a - n/a - Transmammary])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Transmammary])	
										Neonatal disorder (n/a - Recovered/Resolved -)			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Rash papular (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - n/a - n/a])		
										Rash pruritic (n/a - Not Recovered/Not Resolved - ),			
										Skin reaction (n/a - Not Recovered/Not Resolved - )			
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	ICSR
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Haematemesis (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Vomiting (n/a - Not Recovered/Not Resolved - )			
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
										Recovered/Resolved	Transmammary])		-

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EU-EC- 10010682417	18/11/2021	Spontaneous	Healthcare	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),	[TOZINAMERAN] (S - COVID-19	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - [n/a - n/a - 0ral]),  [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - 0ral]),  [ATORVASTATIN, ATORVASTATIN, CALCIUM, ATORVASTATIN CALCIUM, TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - 0ral]),  [FUROSEMIDE, FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - 0ral])	ICSR
EU-EC- 10010668451	17/11/2021	Spontaneous	Healthcare	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	ICSR
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 Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - n/a])	Not reported	ICSR
EU-EC- 10010672730	17/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Resolved - )  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	ICSR
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	ICSR
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])	ICSR
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]	Not reported	ICSR
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	ICSR

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										- 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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Infantile vomiting (n/a - Recovered/Resolved - Other Medically Important Condition),	Transmammary])		
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			
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 - ),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSF
										Somnolence (n/a - Unknown - Other Medically Important Condition)			
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),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Recovered/Resolved - Other Medically Important Condition),	Transmammary])		
										Pyrexia (n/a - Recovered/Resolved - ),			
										Rash (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Rash maculo-papular (36h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010585814	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Eructation (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	ICSR
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} -	Not reported	ICSR
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),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	[MENINGOCOCCAL GROUP B VACCINE] (C - n/a - n/a - [1d - n/a - Intramuscular]),	ICSR
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	Transmammary])	[N. MENINGITIDIS GROUP C POLYSACCHARIDE, N. MENINGITIDIS GROUP Y POLYSACCHARIDE,	
										Infantile vomiting (4d - Recovered/Resolved - Other Medically Important Condition)		NEISSERIA MENINGITIDIS GROUP A POLYSACCHARIDE, NEISSERIA MENINGITIDIS GROUP W135 POLYSACCHARIDE, N. MENINGITIDIS GROUP C POLYSACCHARIDE, NIEISSERIA	

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												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	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10010580137	08/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	Medically Important Condition)  Exposure during pregnancy (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
										Rash maculo-papular (2wk - Recovered/Resolved - Other Medically Important Condition), Rash pruritic (14d -			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010584720	08/11/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Irritability (24h - Recovered/Resolved - ),	applicable - [n/a - n/a - n/a])		
										Nasopharyngitis (24h			
										Recovered/Resolved - ), Rhinorrhoea (24h -			
EU-EC- 10010574630	07/11/2021	Spontaneous		Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Recovered/Resolved - ) Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	Transmammary])		
										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)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Pyrexia (n/a - Unknown - Other Medically Important Condition),	n/a - Transmammary])		
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010562085	05/11/2021	Spontaneous	Non Healthcare	Non European	Not available	2 Months	Not Specified	Female	Yes	Diarrhoea (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN]	[FLUCLOXACILLIN, FLUCLOXACILLIN	<u>ICSR</u>

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			Professional	Economic Area		- 2 Years				- Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a -	SODIUM MONOHYDRATE] (C -	
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	Transmammary])	Mastitis - n/a - [7d - n/a - n/a])	
										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)			
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICSR</u>
										Recovering/Resolving - ), Haemorrhage (4d -			
EU-EC-	04/11/2021	Spontaneous	Healthcare	Non	Not	2	Not	Not	Yes	Recovering/Resolving - Other Medically Important Condition) Breast milk	COMIRNATY	Not reported	ICSR
10010553551	0-11/2021	Spontaneous	Professional	European Economic Area				Specified	163	substitute intolerance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<u>ICSK</u>
										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)			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Somnolence (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	02/11/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	Vomiting (n/a - Not Recovered/Not Resolved - ) Dizziness (57d - Not	COMIRNATY	Not reported	ICSR
10010513457		pontanicous	Healthcare Professional	Economic	available	Months - 2 Years	, wait	. Gridic		Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ason .
										Nausea (57d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (57d - Not Recovered/Not			

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										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	ICSR
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	ICSR
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	ICSR
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/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010481752	29/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	- 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	ICSR
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	ICSR
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	ICSR
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	ICSR
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 - Transmammary])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
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 - Transmammary])	Not reported	ICSR

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EU-EC- 10010420145	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	milk (n/a - Unknown - ),  Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),  Viral infection (n/a - Recovering/Resolving - Other Medically Important Condition)  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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Infant irritability (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010421629	25/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	2 Months	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area		- 2 Years				- ), Haematochezia (2d - Recovered/Resolved - Other Medically Important Condition)	(S - n/a - n/a - [n/a - n/a - n/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	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
										Restlessness (n/a - Recovering/Resolving - )			
EU-EC- 10010397155	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	milk (n/a - Unknown - Other Medically Important Condition), Infantile vomiting (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Pyrexia (n/a - Unknown - Other Medically Important Condition)			
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 - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
										Poor feeding infant (1d - Recovered/Resolved -),			
										Restlessness (1d - Recovered/Resolved - ),			
										Screaming (1d - Recovered/Resolved - )			
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} -	Not reported	ICSR
EU-EC-	22/10/2021	Spontaneous	Healthcare	Non	Not	2	Not	Female	Yes	Exposure via breast	Intramuscular]) TOZINAMERAN	Not reported	ICSR

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10010404020			Professional	European Economic Area	available	Months - 2 Years	Specified			milk (n/a - Unknown - ), Serum sickness (n/a - Recovering/Resolving	[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	- Life Threatening)  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} -	Not reported	ICSR
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	Transmammary]) COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010388104	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Medically Important Condition) Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010390964	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Condition) 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	ICSR
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])	ICSR
EU-EC- 10010391848	21/10/2021	Spontaneous	Non Healthcare Professional		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	ICSR
EU-EC- 10010375840		Spontaneous	Healthcare Professional		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),  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	ICSR
EU-EC- 10010378677	20/10/2021	Spontaneous	Healthcare	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	ICSR

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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	ICSR
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	ICSR
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	ICSR
EU-EC- 10010342147	17/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	- 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	ICSR
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	ICSR
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	ICSR
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	ICSR
EU-EC- 10010337329		Spontaneous	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 - )		Not reported	ICSR
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	ICSR
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	ICSR

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EU-EC-	13/10/2021	Spontaneous	Non	Non	Not	2	Not	Female	Yes	Important Condition) Exposure via breast	TOZINAMERAN	Not reported	ICSR
10010305904		·	Healthcare Professional	European Economic Area	available	Months - 2 Years	Specified			milk (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	Transmammary])		
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	Transmammary])		
										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)			
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										milk (n/a - Unknown - ),  Restlessness (n/a -	1{DF} - n/a])		
										Recovering/Resolving - )			
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 -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Exposure via breast milk (n/a - Unknown	applicable - [n/a - 1{DF} - n/a])	[DESOGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010309882	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months	Not Specified	Female	Yes	Cough (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
						Years				Exposure via breast milk (n/a - Unknown - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Unknown - ),			
										Malaise (n/a - Unknown - ),			
										Nasopharyngitis (n/a - Unknown - ),			
										Pyrexia (n/a - Unknown - ),			
										Somnolence (n/a - Unknown - )			
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	ICSR

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										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	Not Specified	Female	Yes	Feeling jittery (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
						Years				Maternal exposure timing unspecified (n/a - Not Recovered/Not Resolved - ),	immunisation - n/a - [n/a - n/a - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Afterbirth pain - n/a	ICSR
										Exposure via breast milk (n/a - Unknown - ),	n/a - Transmammary])	- [n/a - n/a - Transmammary]), [CETIRIZINE	
										Infant irritability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		DIHYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - Transmammary]),	
										Nasal congestion (n/a - Unknown - Other Medically Important Condition),		[MOMETASONE FUROATE, MOMETASONE FUROATE MONOHYDRATE] (C - Seasonal allergy -	
										Respiratory tract infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		n/a - [n/a - n/a - Transmammary]), [PARACETAMOL] (C - Afterbirth pain - n/a - [n/a - n/a - Transmammary]),	
										Sneezing (n/a - Unknown - Other Medically Important Condition)		[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])	
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	Transmammary])		
										Infant sedation (1d - Recovered/Resolved - Other Medically Important Condition)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Maternal exposure during pregnancy (n/a - Unknown - ),	applicable - [n/a - 1{DF} - n/a])		
										Neonatal asphyxia (n/a - Not Recovered/Not Resolved - Life Threatening),			
										Tremor (n/a - Not Recovered/Not Resolved - Life Threatening)			
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	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-	12/10/2021	Spontaneous	Non	Non	Not	2	Not	Female	Yes	milk (n/a - Unknown - )	TOZINAMERAN	Not reported	ICSR
20 20	12, 10, 2021	Sportunicous		1011				. Citiale	103	, succimilar	, SZIIVAI ILIVAIN		ILUK

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10010294311			Healthcare Professional	European Economic Area	available	Months - 2 Years	Specified			discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a -		
										Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Transmammary])		
										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)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
										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)			
EU-EC- 10010295121	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Months - 2 Years	Not Specified	Female	No	Accidental exposure to product by child (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										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)			
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	ICSR

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Healthcare   Professional Record   Profess											Rash (1d - Recovered/Resolved - Other Medically Important Condition), Rash neonatal (n/a - Unknown - Other Medically Important			
EU-EC-   10/10/2021   Spontaneous   Non   Not   Spontaneous   Non   Not   Spontaneous   Non   Not   Spontaneous   Non   Not   Spontaneous   Not   Not   Not   Not   Spontaneous   Not		12/10/2021		Healthcare	European Economic				Female	Yes	tests abnormal (n/a - Unknown - Other Medically Important Condition), Jaundice neonatal (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	ACID] (C - n/a - n/a - [n/a - n/a -	ICSR
Healthcare   European Professional Even   Pr													n/a - n/a - [n/a - n/a - Transplacental])	
EU-EC- 1010227593  11/10/2021 Spontaneous Professional Pr		11/10/2021		Healthcare	European Economic		Months - 2				(n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC-   11/10/2021   Spontaneous   Non   Healthcare   European   Professional   Economic   Area											milk (n/a - Unknown - Other Medically Important	Transmammary])		
EU-EC-   11/10/2021   Spontaneous   Non   Not   European   Professional   Economic   Area											(n/a - Recovering/Resolving - Other Medically Important			
EU-EC- 10010276593  I1/10/2021 Spontaneous Professional Professional Real Professional Real Professional Real Real Real Real Real Real Real Re											- Recovered/Resolved - Other Medically Important			
EU-EC- 10010276593   11/10/2021   Spontaneous   Non   Healthcare   European   Professional   Professional   Area   Not   Specified   Area   Not   Specified   Spec											Recovering/Resolving - Other Medically Important			
Healthcare Professional Profess	 LEC	11/10/2021	Chantanagua	Non	Nen	Not	2	Net	Nat	Voc	- Unknown - Other Medically Important Condition)	TOZINAMEDANI	Networked	ICCD
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),  Insomnia (2d - Recovered/Resolved - Other Medically Important Condition),  Pyrexia (n/a -		11/10/2021	·	Healthcare	European Economic		Months - 2			res	milk (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICSK</u>
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 -											(n/a - Unknown - Other Medically Important			
- Unknown - Other Medically Important Condition),  Insomnia (2d - Recovered/Resolved - Other Medically Important Condition),  Pyrexia (n/a -											Recovered/Resolved - Other Medically Important			
Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a -											- Unknown - Other Medically Important			
											Recovered/Resolved - Other Medically Important			

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										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	ICSR
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
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	Resolved - ) Cough (n/a - Unknown - 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	ICSR
										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)			
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),	applicable - [1d -	[CYANOCOBALAMIN, FOLIC ACID, POTASSIUM IODIDE, POTASSIUM IODIDE] (C - Pregnancy - n/a - [n/a - n/a - n/a])	
										Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital Anomaly),			
										Limb reduction defect (105d - Fatal - Results in Death, Congenital Anomaly)			
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 - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Unknown - ), Vomiting (n/a - Unknown - )			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - )	Transmammary])		
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Nasopharyngitis (n/a - Recovering/Resolving - Other Medically Important Condition),	Transmammary])		
										Ocular hyperaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Periorbital swelling (n/a - Not Recovered/Not Resolved - Other			

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										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/a3mL - Intramuscular])	Not reported	ICSR
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	ICSR
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 -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition),			
										Infantile vomiting (1d - Recovered/Resolved - Other Medically Important Condition),			
										Regurgitation (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010239957	06/10/2021	Spontaneous			Not available	Months - 2 Years	Not Specified	Female	Yes	- Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
						-				Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	Transmammary])		
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved - )			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
										Hypersomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Transmammary])		
										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),			

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										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	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										milk (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a -			
										Recovering/Resolving - Other Medically Important Condition)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Neonatal anoxia (n/a - Fatal - Results in Death), Neonatal multi-organ	1{DF} - Intramuscular])		
EU EO	04/40/2024			_			7.6			failure (n/a - Fatal - Results in Death)	COMPNATA		reen
EU-EC- 10010195922	01/10/2021	Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Abdominal pain (48h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Diarrhoea (48h - Recovered/Resolved - ),	1{DF} - Transmammary])		
										Infantile spitting up (48h - Recovered/Resolved -)			
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	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										(n/a - Recovered/Resolved - Other Medically Important Condition)	n/a - Transmammary])		
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),	applicable - [1d -	[OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C -	ICSR
										Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other	n/a - Transmammary])	Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a]),  [PARACETAMOL, PARACETAMOL PH.	
										Medically Important Condition), Poor feeding infant (n/a - Unknown -		EUR.] (C - Nasal congestion - n/a - [n/a - n/a - n/a]),	
										Other Medically Important Condition), Rash (n/a -		[RETINOL PALMITATE, ERGOCALCIFEROL BP, NICOTINAMIDE BP, RIBOFLAVIN BP,	
										Recovering/Resolving - Other Medically Important Condition),		ASCORBIC ACID BP, THIAMINE HYDROCHLORIDE BP, PYRIDOXINE HYDROCHLORIDE	
										Urine output decreased (n/a - Unknown - Other Medically Important Condition)		BP, RETINOL PALMITATE, ERGOCALCIFEROL PH. EUR., NICOTINAMIDE BP,	
												RIBOFLAVIN BP, ASCORBIC ACID BP, THIAMINE HYDROCHLORIDE BP, PYRIDOXINE	
												HYDROCHLORIDE BP, RETINOL PALMITATE, THIAMINE HYDROCHLORIDE,	
ttps://dap.on	na ourona	eu/analytic	eleaw dilac	20								ASCORBIC ACID, ERGOCALCIFEROL,	26/6

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												NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - Premature baby - n/a - [n/a - n/a - n/a]), [SODIUM FEREDETATE, SODIUM FEREDETATE TRIHYDRATE] (C - Premature baby - 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])	n/a]) Not reported	ICSR
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	ICSR
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	ICSR
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition)	Transmammary])		
EU-EC- 10010148558	28/09/2021	Spontaneous	Healthcare	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 -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	[IBUPROFEN] (C - Teething - n/a - [n/a - n/a - n/a])	ICSR
										Unknown - Other Medically Important Condition)			
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 -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Recovering/Resolving - Other Medically Important Condition),	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	28/00/2021	Spontaneous	Non	Non	Not	2	Not	Female	No	Poor quality sleep (n/a - Unknown - Other Medically Important Condition) Ear pain (n/a -	TOZINAMERAN	Not reported	ICSR
10010152362	_0, 00, 2021	Sportuneous	Healthcare Professional	European Economic Area	available		Specified	. Griule	.10	Recovering/Resolving - Other Medically Important Condition),		sc reported	<u> </u>

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Section   Page											- Other Medically Important Condition),			
Secondary Special Conference											(n/a - Unknown - Other Medically Important			
Building											Recovering/Resolving - Other Medically Important			
EU-EC   22/09/2022   Sportlaneous   Men   Heathcare   Coronne   Professional   Coronne   Coron											Not Recovered/Not Resolved - Other Medically Important			
Peathcase   Professional Prof											Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- EU-EC- 27/09/2021 Spontaneous Non Non Professional European		28/09/2021	Spontaneous	Healthcare	Economic				Female	No	(n/a - Not Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
ELFEC- 10010154987  Zer/09/2021 Spontaneous Non Healthcare Economic Professional Area Non Healthcare Economic Professional Area Non Healthcare Economic Non Healthcare Economic Non Healthcare Economic Non Healthcare Economic Non Not Recovered (Professional Economic Non Not Non Not Non Not Non Not Non Not Non Not Not Non Not Not Non Not Non Not Non Not Not Non Not Not Non Not											(n/a - Not Recovered/Not Resolved - Other Medically Important			
											Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-   10010135247   27/09/2021   Spontaneous   Healthcare   Professional   Professional   Not   European   Road   Professional   Not   European   Road   Professional   Road   Professional   Road   Roa		28/09/2021	Spontaneous	Healthcare	Economic		Months - 2	Infant	Male	No	Recovered/Resolved -), Pyrexia (1d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
Professional   European   Economic Area   Professional   European   Economic Area   Professional   European   Economic Area   Professional   European   European   European   European   European   Professional   Economic Area   Professional   European   Professional   Economic Area   Professional Economic											Recovered/Resolved	[Intramuscular])		
EU-EC- 10010135343  EU-EC- 10010136222  EU-EC- 10010136224  EU-EC- 10010136224  EU-EC- 10010136225  EU-EC- 10010136225  EU-EC- 10010136225  EU-EC- 10010136225  EU-EC- 10010136225  EU-EC- 1001013626  E		27/09/2021	Spontaneous		European Economic		Months - 2		Male	Yes	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
Healthcare Professional European Professional European Professional	FILEC	27/00/2021	Constant	Nava	Nam	Net	2	Note	NA-1-	W	milk (n/a - Unknown - Other Medically Important Condition)	Transmammary])	TRUPPOSEN	TCCD
EU-EC-  27/09/2021 Spontaneous Non Healthcare Professional Economic Area  Not Recovering/Resolving - Other Medically Important Condition)  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)  Pyrexia (n/a - Not Professional Economic Area)  Polyman Not Parameter Not Professional Economic (n/a - Not Recovered/Not		27/09/2021	Spontaneous	Healthcare	European Economic		Months - 2		Маїе	res	Recovering/Resolving - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	[IBUPROFEN, IBUPROFEN SODIUM] (C - Teething - n/a - [2d -	
EU-EC- 10010138222  EU-EC- 10010138224  EU-EC- 1001013824  EU-EC- 1001013824  EU-EC- 1001013824  EU-EC- 10											milk (n/a - Recovering/Resolving - Other Medically Important		, , , <b>,</b>	
EU-EC- 10010138222    Spontaneous   Non Healthcare Professional   Non Area   Not Area   Not Recovered/Not Resolved - Other Medically Important Condition)    Spontaneous   Non Healthcare Professional   Non Healthcare Professional Area   Not Specified   Not Recovered/Not Resolved - Other Medically Important   Not Recovered/Not Recovered											Recovering/Resolving - Other Medically Important			
Healthcare Professional Feconomic Area  Healthcare Professional European Economic Area  Months - 2 Years  Specified   milk (n/a - Unknown - Other Medically Important condition), Infantile vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)  EU-EC- 27/09/2021 Spontaneous Non European Not 2 Infant Female Yes Pyrexia (n/a - COMIRNATY Not reported ICSR											Recovering/Resolving - Other Medically			
EU-EC- 27/09/2021 Spontaneous Non European Not 2 Infant Female Yes Pyrexia (n/a - COMIRNATY Not reported ICSR		27/09/2021	Spontaneous	Healthcare	European Economic		Months - 2		Male	Yes	milk (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Headache - n/a - `	ICSR
EU-EC- 27/09/2021 Spontaneous Non European Not 2 Infant Female Yes Pyrexia (n/a - COMIRNATY Not reported ICSR											(n/a - Not Recovered/Not Resolved - Other Medically Important			
		27/09/2021	Spontaneous					Infant	Female	Yes	Pyrexia (n/a -		Not reported	<u>ICSR</u>

			Professional	Area		- 2 Years				- ), Rhinitis (n/a -	(S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10010143228	27/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Recovered/Resolved -)  Cough (n/a - Recovered/Resolved - Other Medically Important Condition),  Exposure via breast	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										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)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Transmammary])	Not reported	ICSI
										Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	,,,,		
										Infantile vomiting (4d - Recovered/Resolved - Other Medically Important Condition)			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Pyrexia (3d - Recovered/Resolved -)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
										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)			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICS
										Product administered to patient of inappropriate age (n/a - Unknown - ),			
			s/saw.dll?0							Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			29/

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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	ICSR
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										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)			
EU-EC- 10010069609	20/09/2021	Spontaneous	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	ICSR
EU-EC- 10010069804		Spontaneous	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	ICSR
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),	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 -	ICSR
										Premature baby (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		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])	
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	18/09/2021	Spontaneous	Non	European	Not	2	Elderly	Female	No	Fatal - Results in Death) Influenza like illness	COMIRNATY	Not reported	ICSR
10010046212			Healthcare Professional	Economic Area	available	Months - 2 Years				(n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	·	
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	ICSR
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 -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - ), Pyrexia (1d -	,,,,a] <i>)</i>		
EU-EC-	18/00/2021	Spontaneous	Non	Furonosa	Not	0-1	Adult	Female	No	Recovered/Resolved - ) Hypoaesthesia (2d -	COMIRNATY	Not reported	ICCD
E0-EC-	10/09/2021	Spontaneous	INOIT	European	Not	0-1	Addit	Female	ואט	пуровезинезів (20 -	COMIKNALI	Not reported	ICSR

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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 -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010051879	18/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Recovered/Resolved -) 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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	18/09/2021	Spontaneous		European	Not	0-1	Adult	Female	No	Resolved - Other Medically Important Condition) Headache (0d -	COMIRNATY	Not reported	ICSR
10010053302			Healthcare Professional	Economic Area	available	Month				Recovered/Resolved - ), Injection site pain (1d - Recovered/Resolved - )	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/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 Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
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	ICSR
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	ICSR
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	ICSR
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 - )	, .,	Not reported	ICSR
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 (S - COVID-19 - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
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	ICSR
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	ICSR

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										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	Healthcare	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 -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
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	Unknown - )  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	ICSR
EU-EC- 10009989870	14/09/2021	Spontaneous	Healthcare	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	ICSR
EU-EC- 10009972634	12/09/2021	Spontaneous	Healthcare	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/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009968984	11/09/2021	Spontaneous	Healthcare	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/a3mL - Intramuscular])	Not reported	ICSR 32/6

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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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
FIL F0	10/00/2021									(7d - Recovered/Resolved -)	CONTRACT	No.	1.00
EU-EC- 10009966821	10/09/2021	Spontaneous	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	ICS
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	ICSI
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	ICSI
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 -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
										Headache (1d - Recovering/Resolving -), Hot flush (n/a - Recovering/Resolving -)			
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	ICS
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	ICS
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])	FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - Transmammary]),	ICSF
												[NIFEDIPINE] (C - Hypertension - n/a - [n/a - n/a - Transmammary])	
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	Not reported	ICSF
EU-EC- 10009912498	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	- Not Recovered/Not Resolved - ) Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Pyrexia (1d -	Transmammary])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICS
										Recovered/Resolved - ), Rash (n/a - Not Recovered/Not Resolved - )	Transmammary])		
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	ICSF

						- 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 -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
										Recovering/Resolving - Life Threatening)			
:U-EC- .0009893432	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	IC
										Rash (2d - Recovered/Resolved - Other Medically Important Condition),	Transmammary])		
										Urticaria (2d - Recovered/Resolved - Other Medically Important Condition)			
U-EC- .0009867557	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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	IC
										Exposure via breast milk (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Recovered/Resolved - )			
U-EC- 0009868149	02/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adolescent	Male	No	Lymphadenopathy (2wk - Recovered/Resolved -),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	Not reported	IC
										Pain in extremity (2wk - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
U-EC- 0009877264	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),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	IC
										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),			
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E-Feb   Comparison   Production   Producti		02/09/2021	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Partial seizures (1d - Recovered/Resolved - Caused/Prolonged	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSF
Post-second											Recovered/Resolved - Caused/Prolonged			
EU-CF   10,098/2021   Spontamental Not   Section   Sec		01/09/2021	Spontaneous		Economic		Months - 2			No	Recovered/Resolved - Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
EU-EC   13/08/2021   Sportamenous   Non   Healthcare   European   Not   Legislate   Professional   Not   Sportamenous   Non   Healthcare   European   Not   Legislate   Professional   Not   Legislate   Legislate   Not   Legislate   Legislate   Not   Legislate   N		01/09/2021	Spontaneous	Healthcare	Economic		Months - 2		Male	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - 2{DF} -	Not reported	ICS
ELECTIO099810713   Sportaneous   Non   European   Not reported   State   Sportaneous   Non   European   Not reported   State   Sportaneous   Non   European   Not reported   State   Sportaneous   Non   Sport		01/09/2021	Spontaneous	Healthcare	Economic		Months - 2		Male	Yes	Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	Not reported	ICSF
EU-EC- 1009810713 27/08/2021 Spontaneous In Non Healthcare Professional Area Non Healthcare Professional European Professional Area Non Healthcare Professional Area Non Healthcare Professional European Professional Area Non Healthcare Professional European Profess		31/08/2021	Spontaneous	Healthcare	Economic		Months - 2		Male	Yes	Crying (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 1009849038  27/08/2021 Spontaneous Non- Professional Profession											Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - ),  Rhinorrhoea (n/a - Not Recovered/Not			
EU-EC- 10009810713   Spontaneous   Professional   P		31/08/2021	Spontaneous	Healthcare	Economic		Months - 2		Female	Yes	Asthenia (n/a - Not Recovered/Not Resolved - ), Discomfort (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	Not reported	ICSI
Purpersional Professional Profe		27/08/2021	Spontaneous	Healthcare	European Economic		Months - 2		Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	PARACETAMOL PH. EUR.] (C - n/a - n/a -	ICSF
(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)		27/08/2021	Spontaneous	Healthcare	European Economic		Months - 2			Yes	Important Condition) Crying (n/a - Unknown - Other Medically Important Condition), Exposure via breast milk (n/a - Unknown	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
(n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Poor feeding infant (n/a - Unknown - Other Medically Important Condition)											(n/a - Unknown - Other Medically Important Condition),			
(n/a - Unknown - Other Medically Important Condition)											(n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
EU-EC-   27/08/2021   Spontaneous   Non   European   Not   0-1   Infant   Female   No   Rash morbilliform   COMIRNATY   Not reported   IC	EU-EC-	27/08/2021	Spontaneous	Non	European	Not	0-1	Infant	Female	No	(n/a - Unknown - Other Medically	COMIRNATY	Not reported	ICSR

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			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/a3mL - Intramuscular])	Not reported	ICSR
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 -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
										Recovering/Resolving - Other Medically Important Condition)			
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	ICSR
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 - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Irritability (n/a - Unknown - )			
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										milk (n/a - Unknown - )	Transmammary])		
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	ICSR
EU-EC- 10009802441	26/08/2021	Spontaneous	Healthcare	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	ICSR
EU-EC- 10009784890	25/08/2021	Spontaneous	Non Healthcare Professional		Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	Yes	Agitation (n/a - Recovering/Resolving - ), Crying (n/a - Recovering/Resolving - )	(S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
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),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICSR</u>
										milk (n/a - Unknown - )	n/a - Transmammary])		
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Recovered/Resolved - ),  Vomiting (2d - Recovered/Resolved	1{DF} - n/a])		
EU-EC-	23/08/2021	Spontaneous		European	Not	0-1	Infant	Female	Yes	- ) Dehydration (2d -	COMIRNATY	Not reported	ICSR
10009761163			Healthcare Professional	Economic Area	available	Month				Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -		
										Diarrhoea (2d - Recovered/Resolved - Other Medically Important	Intramuscular])		

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										Condition),			
										Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009762070	23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Cough (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 reported	ICSR
										Pyrexia (n/a - Recovered/Resolved - ),			
										Respiration abnormal (n/a - Recovered/Resolved -)			
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])	ICSF
EU-EC- 10009752665	21/08/2021	Spontaneous	Healthcare	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} -	Not reported	ICSR
EU-EC- 10009752770	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	2 Months	Infant	Male	Yes	- )  Constipation (n/a - Not Recovered/Not Resolved - ),	Transmammary])  COMIRNATY  [TOZINAMERAN]  (S - COVID-19	Not reported	ICSE
			Trorcasional	Aica		Years				Exposure via breast milk (n/a - Not Recovered/Not Resolved - )	immunisation - Unknown - [n/a - 1{DF} - Transmammary])		
EU-EC- 10009752782	21/08/2021	Spontaneous	Healthcare	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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC-	20/00/2024	Carachana	11 lik	F	N-+	2	Niet	N4-1-	V	Resolved - )	Transmammary])	Networked	Tech
10009740844	20/08/2021	Spontaneous	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	ICSR
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										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)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Transplacental])	Not reported	ICSF
										Foetal distress syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important			

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										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	ICSR
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	ICSR
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	ICSR
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	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009691077	16/08/2021	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Condition) 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	ICSR
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	ICSR
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	ICSR
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	ICSR
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	ICSR
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	ICSR

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										Recovered/Resolved - ), Rhinorrhoea (n/a - Recovered/Resolved - ), Sleep disorder (n/a - Recovered/Resolved - ),	n/a - Transmammary])		
										Sneezing (n/a - Recovered/Resolved			
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	ICSR
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Insomnia (n/a - Not Recovered/Not Resolved - ),			
										Somnolence (n/a - Not Recovered/Not Resolved - )			
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	[TOLFENAMIC ACID] (C - Migraine - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-	12/08/2021	Spontaneous	Non	European	Not	2	Not	Female	No	Recovered/Resolved - ) Pyrexia (n/a -	Transmammary]) COMIRNATY	Not reported	ICSR
10009661118	,,,,,		Healthcare Professional	Economic	available		Specified			Recovering/Resolving - ),  Vomiting projectile (n/a - Recovering/Resolving - )	[TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular])		
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
										Infantile apnoea (n/a - Unknown - Other Medically Important Condition),			
										Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation)			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	Transmammary])		
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										milk (n/a - Unknown - ), Malaise (2d - Recovered/Resolved - )			
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]),	ICSR

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										Hypoxic-ischaemic encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Small for dates baby (n/a - Unknown - Caused/Prolonged	[n/a3mL - Intramuscular])	[LEVOTHYROXINE] (C - Hypothyroidsim - 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	Hospitalisation)  Exposure via breast milk (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
										Pyrexia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	,,,,		
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	ICSR
EU-EC- 10009639260		Spontaneous	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	ICSR
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition)	Transmammary])		
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										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)			
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Recovered/Not Resolved - )	Transmammary])		
EU-EC- 10009627814	09/08/2021	Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Abnormal behaviour (n/a - Unknown - ),  Discomfort (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - ),	n/a - Transmammary])		
										Restlessness (n/a - Unknown - )			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Nasopharyngitis (n/a - Unknown - ),  Pyrexia (n/a - Unknown - ),			
										Rhinorrhoea (n/a -			

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I										Unknown - ),			
										Suspected COVID-19 (n/a - Unknown - )			
EU-EC- 10009631536	09/08/2021	Spontaneous	Healthcare	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),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental -	Not reported	ICS
										Premature baby (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	More in ICSR])		
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Product administered to patient of inappropriate age (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009614110	06/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Crying (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Insomnia (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving			
-11 50	05 (00 (000)									-)	T0771141450411		
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	Transmammary])		
										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),			
							1	1	1	T. Control of the Con	1		1
										Urine output decreased (n/a - Unknown - Other			

										Medically Important			
EU-EC-	06/08/2021	Spontaneous		European	Not	2	Not	Male	No	Condition) Diarrhoea (n/a -	COMIRNATY	Not reported	ICS
10009617434			Healthcare Professional	Economic Area	available	Months - 2 Years	Specified			Unknown - ),  Exposure via breast milk (n/a - Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/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 - ),	Transmammary])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Rash (n/a - Unknown - )	applicable - [1d - n/a - Transmammary])		
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
										Recovered/Resolved - )	n/a - Transmammary])		
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Injection site pain (1d - Recovered/Resolved	applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10009598587	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2	Infant	Male	Yes	Exposure via breast milk (1d - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
						Years				Pyrexia (1d - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Vomiting (1d - Recovered/Resolved			
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC- 10009599069	05/08/2021	Spontaneous	Healthcare	European Economic	Not available	2 Months	Infant	Female	Yes	(n/a - Unknown - ) Exposure via breast milk (n/a - Unknown	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
			Professional	Area		- 2 Years				Poor feeding infant (n/a - Not Recovered/Not Resolved - )	immunisation - Not applicable - [n/a - 1{DF} - n/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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [n/a - 150mg - Transplacental]),	ICS
										Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition),	n/a - Transplacental])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 20mg - Transplacental]),	
										Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically		[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 20mg - n/a]),	
										Important Condition)		[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])	
EU-EC- 10009590574	04/08/2021	Spontaneous	Healthcare	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	ICS

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EU-EC- 10009569908	03/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2	Not Specified	Female	No	Insomnia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a -	Not reported	ICS
						Years				Irritability (n/a - Unknown - )	[n/a - n/a - n/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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	IC
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 -	Not reported	ICS
EU-EC- 10009539219	30/07/2021	Spontaneous	Healthcare	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 -)	n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10009539239	30/07/2021	Spontaneous	Healthcare	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	ICS
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	ICS
EU-EC- 10009543465	30/07/2021	Spontaneous		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	IC
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	IC
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 Resolved - ),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	[VALSARTAN, AMLODIPINE BESILATE] (C - Hypertension - n/a - [9mo - 5mg - Oral]), [VINPOCETINE] (C - Cerebrovascular disorder - n/a - [n/a - 10mg - Oral])	ICS
EU-EC- 10009529762	29/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Not Recovered/Not Resolved - ) Asthenia (72h - Recovered/Resolved - ), Headache (72h - Recovered/Resolved - ), Lymphadenopathy (72h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a3mL - Intramuscular])	Not reported	ICS

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										- ), Nausea (72h - Recovered/Resolved - ), Pyrexia (72h -			
EU-EC- 10009534678	29/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Recovered/Resolved -) 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	ICSR
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	20/07/2021	Spontaneous	Non	Furancan	Not	2	Infant	Female	No	Somnolence (n/a - Not Recovered/Not Resolved - )	COMIRNATY	Not reported	ICCD
10009535443	29/07/2021	Sportaneous	Healthcare Professional	European Economic Area	available	Months - 2 Years		remale	NO	milk (n/a - Not Recovered/Not Resolved - ), Somnolence (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009515400	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Adult	Male	No	Resolved - ) 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	ICSR
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	ICSR
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	ICSR
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	ICSR
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	ICSR
EU-EC- 10009518248	28/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthenia (0d - Recovered/Resolved - ), Fatigue (0d - Recovered/Resolved - ), Headache (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	28/07/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	Recovered/Resolved - ) Fatigue (3d -	COMIRNATY	Not reported	ICSR
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			Healthcare Professional	Economic Area	available	Months - 2 Years				Recovered/Resolved - ), Hypotonia (3d - Recovered/Resolved - ),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])		
										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 - )			
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 -),	- n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
										Sleep disorder (1d - Recovering/Resolving -),	Intramuscular])		
FILES	20/07/2021	Caratana	New	<b>-</b>	Net		Net	Mala	No	Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - )			TCCD
EU-EC- 10009520401	28/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
	28/07/2021	Spontaneous	Healthcare	Economic		Months - 2		Male	No	Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
		Spontaneous	Healthcare Professional	Economic		Months - 2		Male Male	No	Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported  Not reported	
10009520401			Healthcare Professional	European Economic	available	Months - 2 Years	Specified			Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) Epistaxis (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -		ICSR
10009520401 EU-EC-			Healthcare Professional Non Healthcare	European Economic	available  Not	Months - 2 Years	Specified			Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) Epistaxis (1d - Recovered/Resolved - ), Epistaxis (1d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not		
10009520401 EU-EC-			Healthcare Professional Non Healthcare	European Economic	available  Not	Months - 2 Years	Specified			Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) Epistaxis (1d - Recovered/Resolved - ), Epistaxis (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise		
10009520401 EU-EC-			Healthcare Professional Non Healthcare	European Economic	available  Not	Months - 2 Years	Specified			Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somnolence (n/a - Unknown - ) Epistaxis (1d - Recovered/Resolved - ), Epistaxis (1d - Recovering/Resolving - ), Influenza like illness (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise		
10009520401 EU-EC-			Healthcare Professional Non Healthcare	European Economic	available  Not	Months - 2 Years	Specified			Recovering/Resolving - ),  Somnolence (1d - Recovering/Resolving - )  Decreased appetite (n/a - Unknown - ),  Pyrexia (n/a - Unknown - ),  Somnolence (n/a - Unknown - )  Epistaxis (1d - Recovered/Resolved - ),  Influenza like illness (1d - Recovered/Resolved - ),  Injection site pain (1d - Recovered/Resolved - ),  Injection site pain (1d - Recovered/Resolved - ),  Injection site pain (1d - Recovering/Resolving - ),  Injection site pain (1d - Recovering/Resolving Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise		
10009520401 EU-EC-			Healthcare Professional Non Healthcare	European Economic	available  Not	Months - 2 Years	Specified			Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) Epistaxis (1d - Recovered/Resolved - ), Epistaxis (1d - Recovering/Resolving - ), Influenza like illness (1d - Recovered/Resolved - ), Injection site pain (1d - Recovered/Resolved - ), Injection site pain (1d - Injection s	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise		
10009520401 EU-EC-			Healthcare Professional Non Healthcare	European Economic	available  Not	Months - 2 Years	Specified			Recovering/Resolving - ), Somnolence (1d - Recovering/Resolving - ) Decreased appetite (n/a - Unknown - ), Pyrexia (n/a - Unknown - ) 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 - ), Injection site pain (1d - Recovering/Resolving - ), Nasopharyngitis (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise		
10009520401 EU-EC-			Healthcare Professional Non Healthcare	European Economic	available  Not	Months - 2 Years	Specified			Recovering/Resolving - ),  Somnolence (1d - Recovering/Resolving - )  Decreased appetite (n/a - Unknown - ),  Pyrexia (n/a - Unknown - ),  Somnolence (n/a - Unknown - )  Epistaxis (1d - Recovered/Resolved - ),  Influenza like illness (1d - Recovered/Resolved - ),  Injection site pain (1d - Recovered/Resolving - ),  Nasopharyngitis (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise		

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										- ), 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 - ), Sneezing (1d - Recovering/Resolving - ), Vision blurred (1d - Recovered/Resolved - ), Vision blurred (1d - Recovered/Resolved - ),			
EU-EC- 10009495876	27/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Recovering/Resolving - )  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Infantile vomiting (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a -	n/a - Transmammary])		
										Recovered/Resolved - Other Medically Important Condition)			
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	ICSR
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	ICSR
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	ICSR
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	ICSR
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/a3mL - Transmammary])	Not reported	ICSR
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	ICSR

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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	Rash erythematous (n/a - Recovered/Resolved - Other Medically Important Condition),  Urticaria (n/a - Unknown - Other Medically Important Condition)  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),  Growth failure (n/a - Unknown - Other Medically Important Unknown - Other Medically Important Unknown - Other Medically Important	n/a - Transmammary])  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])	ICSR
EU-EC- 10009435494	21/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Condition)  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	ICSR
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	ICSR
EU-EC- 10009431105		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	- 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),  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),  Restlessness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Restlessness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		Not reported	ICSR
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	ICSR
EU-EC- 10009383924	16/07/2021	Spontaneous	Healthcare	European Economic Area	Not available	- 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	ICSR
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	<u>ICSR</u>

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						- 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	Healthcare	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	ICSI
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	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSI
										- Congenital Anomaly, Other Medically Important Condition)			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a -	ICSF
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	Transmammary])	n/a])	
										Infantile vomiting (n/a - Unknown - )			
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	ICSF
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	ICSF
EU-EC-	13/07/2021	Spontaneous		European	Not	2	Infant	Male	Yes	Important Condition) Exposure via breast	COMIRNATY	Not reported	ICSF
10009349807			Healthcare Professional	Economic Area	available	Months - 2 Years				milk (n/a - Unknown - ), Poor feeding infant (n/a - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009339701	12/07/2021	Spontaneous	Healthcare	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	ICSF
EU-EC- 10009321662		Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (1d - Recovering/Resolving - )	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
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	ICSR

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										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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
						rears				Vomiting (0d - Recovered/Resolved - )	applicable - [n/a - 1{DF} - n/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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Somnolence (n/a - Not Recovered/Not Resolved - )			
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 - ),	- n/a -	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - )	Intramuscular])		
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	ICSR
EU-EC- 10009282163	06/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
						Years				Pyrexia (n/a - Recovered/Resolved - )	immunisation - Not applicable - [n/a - 1{DF} - n/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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	n/a - Transmammary])		
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										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			

								 		Medically Important			
EU-EC- 10009258639	05/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Condition)  Anosmia (n/a - Recovered/Resolved - ),  Headache (n/a - Recovered/Resolved - ),  Lymphadenopathy (n/a - Recovered/Resolved	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10009237030	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	- ), Pyrexia (n/a - Recovered/Resolved - ) Constipation (6d - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSI
										Exposure via breast milk (n/a - Recovering/Resolving - Other Medically Important Condition), Nasopharyngitis (6d	Talestallina ()		
										Recovering/Resolving - Other Medically Important Condition), Pyrexia (6d - Recovering/Resolving - Other Medically			
EU-EC-	02/07/2021	Spontaneous	Non	European	Not	0-1	Infant	Female	Yes	Important Condition), Weight decreased (n/a - Recovering/Resolving - Other Medically Important Condition) Abdominal pain (n/a	COMIRNATY	Not reported	ICSF
10009237717			Healthcare Professional	Economic Area	available	Month				- Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-	02/07/2021	Spontaneous	Healthcare	European	Not	0-1	Not	Female	No	Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ) Fatigue (24h -	COMIRNATY	Not reported	ICSF
10009239701	<b>32</b> , 37, 4342		Professional	Economic Area	available	Month	Specified			Recovered/Resolved - ), Influenza like illness (24h - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])		100
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	ICSF
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,	ICSR
EU-EC-	30/06/2021	Spontaneous		European	Not	2	Adult	Female	Yes	Exposure via breast	COMIRNATY	SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Transmammary]) Not reported	ICSR
10009208487			Healthcare Professional	Economic Area	available	Months - 2 Years				milk (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		

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										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	ICSR
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSF
										Pyrexia (n/a - Recovering/Resolving - )	Transmammary])		
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 [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Unknown - ), Restlessness (n/a - Not Recovered/Not Resolved - ),			
										Sleep disorder (n/a - Not Recovered/Not Resolved - )			
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	ICSR
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [4d3mL - Intramuscular])	Not reported	ICSR
										- ), Headache (4d - Recovered/Resolved - ),	7		
										Myalgia (4d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved - )			
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	ICSR
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Peripheral swelling (3d - Recovered/Resolved - Other Medically Important Condition)			
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 -	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]),	ICSR
										Recovered/Resolved - ), Decreased appetite		[LEVOTHYROXINE SODIUM] (C - Autoimmune	
										•			

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										(2d -   Recovered/Resolved  - ),		hypothyroidism - n/a - [n/a - n/a - n/a])	
										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			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a	Not reported	ICSR
										Lymph node pain (n/a - Not Recovered/Not Resolved - ),	- [n/a3mL - Intramuscular])		
										Lymphadenopathy (17h - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
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	ICSR
EU-EC- 10009101906	22/06/2021	Spontaneous	Non Healthcare	European	Not available	2 Months	Elderly	Male	No	Breast pain (3d - Not Recovered/Not		Not reported	ICSR
			Professional			- 2 Years				Resolved - Caused/Prolonged Hospitalisation)	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
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	ICSR
EU-EC- 10009089559	21/06/2021	Spontaneous	Healthcare	European Economic	Not available	2 Months	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Unknown	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area		- 2 Years				Fatigue (n/a - Not Recovered/Not Resolved - )	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Rhinorrhoea (n/a - Recovered/Resolved - ),	applicable - [n/a - n/a - Transmammary])		
										Upper respiratory tract infection (n/a - Recovered/Resolved - Other Medically Important Condition)			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Mood swings (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Off label use (n/a - Unknown - ), Product use issue			
EU-EC-	18/06/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	(n/a - Unknown - ) Pruritus (2wk -	COMIRNATY	[NEBIVOLOL] (C -	ICSR
10009063293	, 50, 2021		Healthcare Professional	Economic	available	Months - 2 Years				Recovered/Resolved	COVID-19 MRNA VACCINE (NUCLEOSIDE	n/a - n/a - [n/a - 5mg - Oral])	-551

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											MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [3wk3mL - Intramuscular])		
EU-EC- 10009045640	17/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Dermatitis atopic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Transmammary])	Not reported	ICSR
EU-EC- 10009051818	17/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - ), Swelling of eyelid (n/a - Not Recovered/Not Resolved - )	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009035884	16/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Elderly	Male	No	Spinal fusion surgery (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
10009040121	16/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Vomiting projectile (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Oral])	Not reported	ICSR
EU-EC- 10009040948	16/06/2021	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 [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10009022762	15/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Gastrointestinal pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009023481	15/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Influenza like illness (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
10009026916		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	- 2 Years	Not Specified	Male	Yes	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),  Infantile vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Infantile vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Insomnia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10009013107	14/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
10008983697		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	- 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Malaise (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10008965411	10/06/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	2 Months	Not Specified	Not Specified	Yes	Constipation (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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				Economic Area		- 2 Years				Condition),  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - Transmammary])		
										Infant irritability (n/a - Unknown - Other Medically Important Condition)			
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/a3mL - n/a])	Not reported	ICSR
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 - n/a])	Not reported	ICSR
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	ICSR
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	ICSR
EU-EC-		Spontaneous Spontaneous	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)  Dermatitis allergic	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
10008931182	07/00/2021	Sportaneous	Healthcare Professional	Economic Area	available	Months - 2 Years	Liuerry	ridic	NO	(n/a - Unknown - ),  Rash (n/a - Unknown - )	[TOZINAMERAN] (S - Immunisation	Not reported	ICSK
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	ICSR
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	ICSR
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 - n/a])	Not reported	ICSR

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										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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Overfeeding of infant (n/a - Unknown - )	applicable - [1d - n/a - Transmammary])		
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 -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION	Not reported	ICSR
										Unknown - ), Rhinorrhoea (n/a - Unknown - )	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - Not applicable - [n/a -		
EU-EC- 10008822508	28/05/2021	Spontaneous	Healthcare Professional	Non European	Not available	0-1 Month	Not Specified	Male	Yes	Death (n/a - Fatal - Results in Death),	n/a - n/a]) TOZINAMERAN [TOZINAMERAN]	[CRISABOROLE] (C - Dermatitis atopic -	ICSR
				Economic Area						Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental - More in ICSR])	n/a - [n/a - n/a -	
										Meconium aspiration syndrome (n/a - Unknown - Other Medically Important Condition),			
										Premature baby (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008801243	27/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Exposure via breast	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										milk (n/a - Unknown - ), Rash (n/a -	n/a - n/a])		
EU EC	27/05/2021	C	NI	F	Not	2	T. 6 4	NA-1-	V	Recovering/Resolving	COMIDNIATY	Not an arte d	TOCO
EU-EC- 10008801915	27/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ),  Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Not Resolved - )	n/a - n/a])		
EU-EC- 10008803586	27/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Diarrhoea (6d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - )	applicable - [n/a - n/a - n/a])		
EU-EC- 10008806516	27/05/2021	Spontaneous	Healthcare	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	ICSR
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/a3mL - Intramuscular])	Not reported	ICSR
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	ICSR
EU-EC- 10008788572	26/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Decreased appetite (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Irritability (1d - Recovered/Resolved - )			
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	ICSR

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						- 2 Years				Influenza (n/a - Not Recovered/Not Resolved - ),	- n/a - [n/a - n/a - Intramuscular])		
										Injection site pain (1d - Recovered/Resolved -)			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - ),	immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
										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 - )			
EU-EC- 10008774822	25/05/2021	Spontaneous	Healthcare	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	ICSR
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition)	n/a - Transmammary])		
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	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved			
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Unknown - )	n/a - Transmammary])		
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	ICSR
EU-EC- 10008672275	17/05/2021	Spontaneous	Healthcare	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Transmammary])	Not reported	ICSR
										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			
EU-EC-	13/05/2021	Spontaneous		European	Not	2 Months	Not	Female	No	Important Condition) Exposure via breast	COMIRNATY	Not reported	ICSR
10008634274			Professional	Economic Area	available	IMONTHS	Specified			milk (n/a - Unknown  - ),	[TOZINAMERAN] (S - COVID-19		

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						- 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 - ),	COMIRNATY	TECFIDERA 240 MG [DIMETHYL FUMARATE] (C - Multiple sclerosis -	ICSF
										Headache (6d - Recovered/Resolved - ),	n/a])	n/a - [n/a - 480mg - Oral])	
										Influenza like illness (6d - Recovered/Resolved -),			
										Pyrexia (6d - Recovered/Resolved			
										Tremor (6d - Recovered/Resolved - )			
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 - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
										Headache (3d - Recovered/Resolved - ),	- n/a - [n/a - n/a - Intramuscular])		
										Influenza like illness (3d - Recovered/Resolved			
										Limb discomfort (3d			
										Recovered/Resolved			
										Nausea (3d - Recovered/Resolved - )			
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 - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR
										Injection site pain	- n/a - [n/a - n/a - Intramuscular])		
										Recovered/Resolved - ),			
										Malaise (1d - Recovered/Resolved -),			
										Myalgia (1d - Recovered/Resolved - )			
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 -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Irritability (3d - Recovered/Resolved -)			
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),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Myalgia (1d - Not Recovered/Not Resolved - )			
EU-EC- 10008478704	29/04/2021	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2	Infant	Male	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
						Years				Pyrexia (5d - Recovered/Resolved	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Rash (3d - Recovered/Resolved			
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 -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Pyrexia (4d - Recovered/Resolved - )	n/a - Transmammary])		
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not		ICSR
		I				1				Cystitis (n/a -		n/a - n/a]),	

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										Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	
										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 - )			
EU-EC- 10008386439	21/04/2021	Spontaneous		Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				71100		rears				Fever neonatal (3d - Unknown - Other Medically Important Condition),	applicable - [n/a - n/a - Other])		
										Illness (n/a - Unknown - ),			
										Rash (1wk - Unknown - )			
EU-EC- 10008388576	21/04/2021	Spontaneous		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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Neonatal respiratory acidosis (n/a - Recovering/Resolving - ),			
										Premature baby (n/a			
EU-EC-	20/04/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	Recovering/Resolving - ) Chills (n/a -	COMIRNATY	[LEVOTHYROXINE,	ICSR
10008368804	20,01,2021	эропшисов	Healthcare	Economic Area	available	Months - 2 Years	Nadic	remaie		Recovering/Resolving - ),  Decreased appetite		LEVOTHYROXINE SODIUM] (C - n/a -	ICOK
										(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 -),			
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										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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	IC
										Dizziness (n/a - Recovering/Resolving - ), Heart rate increased (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving - )			
U-EC- 0008355561	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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	I
										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)			
I-EC- 008356645	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),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	n/a]),	
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),		KEPPRA [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),		[DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C -	
										Hyperhidrosis (n/a - Unknown - Other Medically Important Condition),		n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C -	
										Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition),		n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a -	
										Pallor (2d - Recovered/Resolved - Other Medically Important Condition),		n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a -	
												n/a]),	-
										Pyrexia (n/a - Unknown - Other Medically Important Condition)		n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C -	

												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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSF
										Fever neonatal (n/a - Recovering/Resolving - Other Medically Important Condition),	,,,,		
										Rash neonatal (n/a - Recovering/Resolving - )			
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
										Malaise (n/a - Unknown - Other Medically Important Condition),	Transmammary])		
										Pyrexia (7d - Recovered/Resolved - Other Medically Important Condition),			
										Viral infection (n/a - Unknown - Other Medically Important Condition)			
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/a3mL - Transmammary])	Not reported	ICSR
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 137ug - Transmammary]),	ICSR
										Exposure via breast milk (n/a - Unknown - ), Nasopharyngitis (n/a	Transmammary])	[SULFASALAZINE] (C - Arthritis - n/a - [n/a - 1000mg - Transmammary])	
										- Unknown - ),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rhinorrhoea (7d - Recovered/Resolved - )			
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - Transmammary])		
										Wheezing (n/a - Recovered/Resolved - )			
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 -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovering/Resolving - ), Influenza (3d -	and an ascular J)		
										Recovering/Resolving - ), Lymphadenitis (3d - Recovering/Resolving			
										- ), Myalgia (3d - Recovering/Resolving - ),			
										Somnolence (3d -			

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										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 -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} -	Not reported	ICSI
										Unknown - ),  Dysgeusia (n/a -	Intramuscular])		
EU-EC-	07/04/2021	Spontaneous	Non	European	Not	2	Infant	Female	Yes	Unknown - ) Crying (n/a -	COMIRNATY	Not reported	ICSF
10008221718	07,01,2021	Spontaneous	Healthcare	Economic Area	available	Months - 2 Years		remaie		Recovering/Resolving - ),  Exposure via breast milk (n/a - Unknown	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	not reported	1001
										Fatigue (n/a - Recovering/Resolving			
										Malaise (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10008177763		Spontaneous	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	ICSF
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),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
										Neuralgia (n/a - Unknown - Disabling)			
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	ICSR
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	ICSF
EU-EC- 10008093826	27/03/2021	Spontaneous		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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Oral])	Not reported	ICSF
EU-EC- 10008083321	26/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Important Condition) 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	ICSR
EU-EC- 10008042963		Spontaneous		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	ICSR

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										Condition),  Pyrexia (2d - Recovered/Resolved	applicable - [n/a - n/a - Oral])		
										- Other Medically Important Condition)			
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	ICSR
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	ICSR
EU-EC- 10007971748	17/03/2021	Spontaneous	Healthcare	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	ICSR
EU-EC- 10007945446	16/03/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adult	Female	No	Asthma (n/a - Unknown - ), Respiratory distress	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10007884848	10/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	(n/a - Unknown - ) Pain in extremity (0d - Not Recovered/Not Resolved - )	Intramuscular])  COMIRNATY  [TOZINAMERAN]  (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10007857596	09/03/2021	Spontaneous	Healthcare	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	ICSR
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		Not reported	ICSR
EU-EC-	09/03/2021	Spontaneous	Non	European	Not	0-1	Adult	Male	No	Hospitalisation, Other Medically Important Condition) Fatigue (18d - Not	COMIRNATY	Not reported	ICSR
10007866820	33,33,232	Sportanicous	Healthcare Professional	Economic	available	Month				Recovered/Not Resolved - ), Feeling cold (18d - Not Recovered/Not Resolved - ), Headache (18d - Not Recovered/Not	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Recovered/Not Resolved - ), Muscle twitching (18d - Not Recovered/Not Resolved - ),			
										Somnolence (18d - Not Recovered/Not Resolved - ),			
EU-EC-	09/03/2021	Spontaneous	Non	European	Not	0-1	Adult	Male	No	(18d - Not Recovered/Not Resolved - ) Headache (2d -	COMIRNATY	Not reported	ICSR
10007866881	,	,	Healthcare Professional	Economic	available	Month				Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	,	
EU-EC- 10007852125	08/03/2021	Spontaneous	Non Healthcare	European Economic	Not available	0-1 Month	Adult	Female	No	Chills (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

			Professional	Area						- ), Muscular weakness (1d - Recovered/Resolved - )	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10007852266	08/03/2021	Spontaneous	Healthcare	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 - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10007852282	08/03/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Infant	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Recovered/Not Resolved - ), Peripheral vascular	indamusculai j <i>j</i>		
										disorder (n/a - Not Recovered/Not Resolved - ),			
										Respiratory distress (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10007852724	08/03/2021	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Infant	Male	No	Abdominal pain (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Pyrexia (2d - Recovered/Resolved			
EU-EC- 10007770028	03/03/2021	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Hypoxia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICS
										Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)	Intramuscular])		
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),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSI
										Infant irritability (n/a - Unknown - Other Medically Important Condition),	Transmammary])		
										Skin exfoliation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSI
										Faeces discoloured (2d - Recovered/Resolved - Other Medically Important Condition),	Transmammary])		
										Headache (3d - Recovered/Resolved - Other Medically Important Condition),			
										Infant irritability (3d			
			 s/saw.dll?0							Recovered/Resolved			63/

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										- Other Medically Important Condition),			
										Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10007664316	19/02/2021	Spontaneous	Healthcare	European Economic	Not available	2 Months	Infant	Female	Yes	Exposure via breast milk (1d - Unknown -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area		- 2 Years				), Listless (1d - Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Pyrexia (1d - Recovered/Resolved - )			
EU-EC- 10007631251	16/02/2021	Spontaneous	Healthcare Professional	European Economic	Not available	2 Months	Adult	Male	No	Dry mouth (n/a - Unknown - ),	[TOZINAMERAN] (S - n/a - Unknown	Not reported	ICSR
				Area		- 2 Years				Hypoaesthesia oral (1d - Recovered/Resolved	- [n/a - n/a - n/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),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
										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			
EU-EC- 10007531350	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Condition)  Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Rash (n/a - Recovered/Resolved - Other Medically Important Condition),	n/a - Transmammary])		
										Urticaria (24h - Recovered/Resolved - Other Medically Important Condition)			
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	ICSR
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/a3mL - Intramuscular])	Not reported	ICSR
EU-EC-	25/01/2021	Spontaneous	Non	European	Not	2	Adult	Female	No	Back pain (5d - Not	COMIRNATY	Not reported	ICSR

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10007420806			Healthcare Professional		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 - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
										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 - )			
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	ICSR
EU-EC- 10007346597	14/01/2021	Spontaneous	Healthcare	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	ICSR
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	ICSR
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	ICSR
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	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										- ), Injection site pain (0d - Recovered/Resolved - )	Indumoscular jy		
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	ICSR
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 -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	[ARTICAINE HYDROCHLORIDE, EPINEPHRINE] (C - Anaesthesia - n/a - [n/a - n/a -	ICSR
										Recovering/Resolving -), Therapeutic product ineffective (4d - Recovering/Resolving	Intramuscular])	Intravenous (not otherwise specified)])	
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 - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Peripheral vascular disorder (0d - Not Recovered/Not Resolved - ),	Intramuscular])		
										Vaccination site reaction (0d - Not Recovered/Not Resolved - )			
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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	ICSR
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	ICSR
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	ICSR
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	ICSR
EU-EC- 10007293339	04/01/2021	Spontaneous	Non Healthcare Professional		Not available	0-1 Month	Adult	Female	No	Chills (0d - Recovering/Resolving - ), Diarrhoea (0d - Recovering/Resolving - )	(S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
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	ICSR
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 - )	(S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR

↑ ↑ ↑ Towns 1 - 480 (All Rows)

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