## Line Listing Report Time run: 30/11/2022 03:07:41

Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Child	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- 10014103779		Spontaneous		Purposes European	Not	- 2	Not Specified	Male	No	Rash papular (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}		ICSR
EU-EC- 10014104013	25/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Years 2 Months - 2 Years	Not Specified	Male	No	Ear haemorrhage (n/a - Fatal - Results in Death),	- Intramuscular use]) TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Epistaxis (n/a - Fatal - Results in Death), Eye haemorrhage (n/a - Fatal - Results in Death, Other Medically Important			
										Condition),  Mouth haemorrhage (n/a - Fatal - Results			
EU-EC- 10014104935	25/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	in Death) Asthenia (n/a - Unknown - ), Diarrhoea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous use])	Not reported	ICSR
										Recovered/Not Resolved - ), Gastrointestinal	,		
										disorder (n/a - Not Recovered/Not Resolved - ), Lethargy (n/a -			
EU-EC- 10014097157	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
										Resolved - ),  Constipation (n/a - Not Recovered/Not Resolved - ),			
										Crying (n/a - Not Recovered/Not Resolved - ),			
										Exposure via breast milk (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10014088668	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Male	Yes	Bradycardia neonatal (45d - Recovering/Resolving - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental])	Not reported	ICSR
										Foetal growth restriction (n/a - Recovering/Resolving - Life Threatening),			
										Maternal exposure during pregnancy (n/a - Recovered/Resolved - ),			
										Neonatal respiratory distress syndrome (n/a -			
										Recovered/Resolved - Life Threatening), Premature baby (n/a - Recovering/Resolving			
EU-EC- 10014091386	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	- Life Threatening) Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Transplacental]),	Not reported	ICSR
										Hospitalisation), Hydranencephaly (13d - Fatal - Results in Death,	[ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID		
										Caused/Prolonged Hospitalisation), Necrotising enterocolitis neonatal	TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID		
										Death, Caused/Prolonged Hospitalisation),	ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM		
										Neonatal seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE,		
										Perinatal stroke (16d - Fatal - Results in Death, Caused/Prolonged	HYDRATED AND ALUMINIUM PHOSPHATE, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID,		

EILEC	21/41/2022	Sportman	Non	Europa	Not	0-1	Ecotus	Not	Vec	Maternal evacure	TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, PERTUSSIS TEILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, ALGELDRATE, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FI	Not procted.	Ices
EU-EC- 10014065254	21/11/2022	Spontaneous		Economic	Not available	0-1 Month	Foetus	Not Specified	Yes	Maternal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly), Pulmonary malformation (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10014067321	21/11/2022	Spontaneous		Economic	Not available		Not Specified	Female	No	Arthralgia (1wk - Recovering/Resolving - ), Asthenia (1wk - Recovering/Resolving - ), Body temperature increased (1wk - Recovering/Resolving - ), Hyperhidrosis (1wk - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10014048984	18/11/2022	Spontaneous			Not available		Not Specified	Male	No	Febrile convulsion (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN (A/BRISBANE/59/2007 REASS. IVR-148), A/BRISBANE/10/2007 REASS. IVR-148), A/BRISBANE/10/2007 REASS. IVR-148), A/BRISBANE/10/2007 REASS. IVR-148), A/BRISBANE/10/2007 REASS. NYMC X-175C), B/FLORIDA/4/2006-LIKE STRAIN (B/BRISBANE/3/2007), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN (USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/BRISBANE/60/2009 (H1N1) PDM09-LIKE STRAIN (A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-518), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-518), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009	

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EU-EC- 10014021274	16/11/2022	Spontaneous		European Economic	Not available	2 Months	Not Specified	Female	No	Epistaxis (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	REASS. NYMC X-187), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, A/TEXAS/50/2012 (H3N2) - DERIVED STRAIN USED (NYMC X-223A), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB- 74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/CHAIFORNIA/7/2009 (H1N1)- DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1)- DERIVED STRAIN USED NYMC X- 181, HAEMAGGLUTININ, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS, NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)- DERIVED STRAIN USED NYMC X- 181, B/BRISBANE/60/2008, INFLUENZA VACCINE] (C - n/a - 1/a - [1d - n/a - n/a]) Not reported	
10014021274			Healthcare Professional		available	- 2	Specified			Recovered/Resolved -	Not applicable - [n/a - 1{DF}		
EU-EC- 10014006851	15/11/2022	Spontaneous	Non	European Economic	Not available	Years 0-1 Month	Infant	Female	Yes	Congenital anomaly (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Deafness (n/a - Not Recovered/Not Resolved - Congenital Anomaly), Foetal exposure during pregnancy (n/a	- Intramuscular use])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transplacental]),  [OMEPRAZOLE] (S - Product used for unknown indication - Not applicable - [n/a - 10mg - Transplacental])	Not reported	ICSR
										- Recovered/Resolved With Sequelae - Congenital Anomaly)			
EU-EC- 10013997237	14/11/2022	Spontaneous	Healthcare Professional		Not available	2 Months - 2 Years	Not Specified	Female	No	Erythema (n/a - Recovering/Resolving - ), Haematoma (n/a - Recovering/Resolving - ), Joint swelling (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013971287	10/11/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Blindness congenital (n/a - Unknown - Other Medically Important Condition), Congenital optic nerve anomaly (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
EU-EC- 10013947236	08/11/2022	Spontaneous	Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (2d - Recovered/Resolved - )	COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC- 10013936755	07/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - 3ug - n/a])	Not reported	ICSR
EU-EC- 10013937458	07/11/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (3d - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (3d - Recovered/Resolved - ), Weight gain poor (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10013913739	03/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN]  (S - Immunisation - n/a - [n/a  - n/a - n/a])	Not reported	ICSR
										Restlessness (2d - Recovered/Resolved -			
EU-EC- 10013915670	03/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	CIMZIA 200 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE [CERTOLIZUMAB PEGOL] (C - Rheumatic disorder - n/a - [n/a - 1{DF} - n/a]),  [SULFASALAZINE] (C - Rheumatic disorder - n/a - [n/a - 2{DF} - n/a]),	ICSF
												[THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - )	
EU-EC- 10013889128	01/11/2022	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Rash (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10013890678	01/11/2022	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	No	Resolved - )  Epidermolysis bullosa (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICS
EU-EC- 10013884304	31/10/2022	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Unknown - ), Rhinorrhoea (n/a -			
EU-EC- 10013840895	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Unknown - )  COVID-19 immunisation (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[DOCONEXENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL	
						rears				Decreased appetite (n/a - Recovering/Resolving -),		ESTERS 90, OMEGA-3-ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C - n/a - n/a - ),	
										Discomfort (n/a - Unknown - ), Exposure via breast		[VITAMIN D] (C - n/a - n/a - )	
										milk (n/a - Unknown - ), Fatigue (n/a - Recovering/Resolving			
										- ), Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10013842089	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Neonatal disorder (n/a - Unknown - ), Restlessness (n/a - Unknown - )			
EU-EC- 10013843250	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abdominal pain (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Exposure via breast milk (n/a - Unknown - ), Restlessness (3d -			
EU-EC- 10013833372	25/10/2022	Spontaneous			Not available		Not Specified	Female	No	Recovered/Resolved - ) Cellulitis (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSE
				Economic Area		- 2 Years				Other Medically Important Condition), Decreased appetite (22d -	Not applicable - [n/a2mL - Intramuscular use])		
										Recovered/Resolved - Other Medically Important Condition), Gingival disorder (n/a			
										- Recovered/Resolved - Other Medically Important Condition), Gingival ulceration			
										(23970min - Recovered/Resolved - Other Medically Important Condition),			
										Inflammation (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition),			

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										Pyrexia (102h - Recovered/Resolved - Other Medically Important Condition),			
										Rash (7d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10013833440	25/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]),	ICS
										Exposure via breast milk (n/a - Unknown - ),		[DESOGESTREL] (C - n/a - n/a - [n/a - 75ug - n/a]),	
	25/10/2022			_						Malaise (n/a - Recovered/Resolved - )		[OMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - 40mg - n/a])	_
EU-EC- 10013833441	25/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Crying (n/a - Recovering/Resolving -), Exposure via breast	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		IC
										milk (n/a - Unknown - ),			
										Infant irritability (n/a - Recovering/Resolving - ),			
EU-EC-	24/10/2022	Spontaneous	Healthcare	European	Not	0-1	Neonate	Ma <b>l</b> e	Yes	Poor quality sleep (n/a - Unknown - ) Congenital	TOZINAMERAN	TOZINAMERAN [TOZINAMERAN]	IC
10013823427	_ 1, 10, 2022	openiance as		Economic Area	available	Month	(Preterm and Term newborns)			hydronephrosis (n/a - Unknown - Congenital Anomaly),	[TOZINAMERAN] (S - COVID-	(C - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]),  [AZITHROMYCIN,	
										Congenital ureteropelvic junction obstruction (n/a - Unknown - Congenital Anomaly),	[DOXYLAMINE HYDROGEN SUCCINATE, PYRIDOXINE HYDROCHLORIDE] (S - Morning sickness - n/a - [n/a - n/a - Transplacental])	AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - Chlamydial infection - n/a - [n/a - n/a - Transplacental]),	
										Foetal exposure during pregnancy (n/a - Unknown - )		[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - Transplacental]),	
												[DIMENHYDRINATE] (C - Nausea - n/a - [n/a - n/a - Transplacental]),	
												[OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - Dyspepsia - n/a - [n/a - n/a - Transplacental])	
EU-EC- 10013823987	24/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Cough (n/a - Unknown - ), Decreased activity	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
				Aica		rears				(n/a - Unknown - ),  Decreased appetite	1,41)		
										(n/a - Unknown - ), Diarrhoea (n/a - Not Recovered/Not			
										Resolved - ),  Hyperpyrexia (5d - Recovered/Resolved -			
										Other Medically Important Condition), Rhinorrhoea (n/a -			
EU-EC- 10013825771	24/10/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	2 Months - 2	Not Specified	Male	No	Unknown - ) Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	IC
				Area		Years				Hospitalisation), Enterovirus infection	n/a])		
										(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Hyperpyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Roseola (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10013826034	24/10/2022	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term	Female	Yes	Hydrocephalus (n/a - Fatal - Results in Death)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	IC
EU-EC- 10013800256	21/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Depressed mood (n/a - Not Recovered/Not Resolved - ),	- Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
						redis				Exposure via breast			

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										milk (n/a - Unknown - ), Restlessness (n/a - Not Recovered/Not			
EU-EC- 10013801798	21/10/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available		Not Specified	Not Specified	Yes	Resolved - ) Abnormal faeces (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional	Area		- 2 Years				Decreased appetite (n/a - Unknown - ),	- n/a - n/a])		
										Diarrhoea (n/a - Not Recovered/Not Resolved - ),			
										Exposure via breast milk (n/a - Unknown - ),			
										Infantile vomiting (n/a			
										Recovering/Resolving - ),			
										Mucous stools (n/a - Unknown - ),			
FU 50	24 /40 /2022			-	No.	0.1		F I.	V.	Retching (n/a - Unknown - )	CONTRACT (TOTAL AND AND		TOOD
EU-EC- 10013801813	21/10/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Exposure via breast milk (n/a - Unknown - ),			
										Hypersomnia (n/a - Recovering/Resolving - ),			
										Infrequent bowel movements (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10013805570	21/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term	Male	No	Acute respiratory distress syndrome (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intrauterine	Not reported	<u>ICSR</u>
							newborns)			Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	use])		
										Hepatic infarction (n/a			
										Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Hypertrophic cardiomyopathy (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Splenic infarction (n/a			
										Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Thrombosis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10013808359	21/10/2022	Spontaneous	Healthcare Professional		Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Apgar score low (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental])	[ANHYDROUS CHOLESTYRAMINE, COLESTYRAMINE, COLESTYRAMINE ANHYDROUS] (C - Diarrhoea - n/a - [n/a - n/a -	ICSR
										Foetal exposure during pregnancy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),		Transplacental])	
										Neonatal respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Premature baby (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10013768782	18/10/2022	Spontaneous		European Economic Area	Not available	- 2	Not Specified	Male	Yes	Asthenia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSR
						Years				Fatigue (n/a - Recovering/Resolving - ),	Transmammary])		
										Listless (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - )			

).11.2022 ( EU-EC- 10013771237		Spontaneous	Healthcare Professional		Not available	Months	Not Specified		No No	ine Listing Repor Pruritus (14d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSI
				Area		- 2 Years				), Rash maculo-papular (14d - Recovered/Resolved -	Not applicable - [n/a3mL - n/a])		
EU-EC- 10013775124	18/10/2022	Spontaneous	Healthcare Professional	European	Not available	Years 2	Not Specified	Female	Yes	Rash maculo-papular (14d - Recovered/Resolved - ) Ankyloglossia congenital (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Congenital musculoskeletal disorder of spine (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Congenital skin dimples (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Developmental delay (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly), Developmental delay (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly),  Eye inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly),  Eye inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Mandibulofacial dysostosis (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a - [n/a - n/a - n/a - [n/a - 1]a - [n/a - n/a - [n/a - n/a - [n/a - n/a - [n/a - 1]a - [n/a - n/a - []a - [n/a - n/a - []a - [	ICS
										Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly),  Neonatal deafness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly),  Total Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other			
										Medically Important Condition), Oculoauriculovertebral dysplasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Ophthalmia neonatorum (n/a -			
										Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal fusion anomaly (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Congenital			
										Anomaly), Selective eating disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			

EU-EC- 10013765234	17/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN]   (S - COVID-19 immunisation -   Not applicable - [n/a - n/a -   Transmammary])	Not reported	ICSF
U-EC- 0013743586	14/10/2022	Spontaneous	Healthcare	European Economic	Not available	2 Months	Infant	Ma <b>l</b> e	Yes	Underweight (n/a - Unknown - ) Pyrexia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
:U-EC- 0013730542	13/10/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	- 2 Years 2 Months - 2 Years	Not Specified	Male	Yes	- )  Abdominal pain upper (n/a - Recovering/Resolving - ),	Not applicable - [1d - 1{DF} - Transmammary]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Crying (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - ), Insomnia (n/a - Unknown - ), Pain (n/a - Unknown -			
:U-EC-	12/10/2022	Spontaneous	Haalthaara	Non	Not	2	Not	Female	No	), Restlessness (n/a - Unknown - ) Cellulitis (n/a - Not	COMIDNATY FTOZINAMEDANI	[COLECALCIFEROL] (C - n/a -	ICS
.0013724629			Professional	European Economic Area	available	Months - 2 Years	Specified			Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (0d - Unknown - ), Product administration error (0d - Unknown - )	(S - n/a - Not applicable - [n/a - n/a - Intramuscular use]),  [ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED ) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS ANTIGEN, STRAIN HM175, INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS ANTIGEN, STRAIN HM175, INACTIVATED, ADSORBED ON ALUMINIUM HYDROXIDE, HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS HM176 STRAIN (INACTIVATED), ALGELDRATE, HEPATITIS	Dose not changed - [n/a - n/a - n/a])	
EU-EC- L0013725949	12/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Overdose (n/a - Unknown - ), Product preparation error (n/a - Unknown	n/a - Intramuscular use]) TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a2mL - n/a])	Not reported	ICS
:U-EC- .0013701219	10/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death), Exposure via breast milk (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICS
EU-EC- 1.0013701751	10/10/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Foetal exposure	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS

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										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10013692453	07/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Diarrhoea (6wk - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
										Haematochezia (6wk - Recovered/Resolved - Other Medically Important Condition),			
EU EC	05/10/2022	Constant	Non	- Francisco	Note	0.1	Note	Famala	NI-	Neutropenia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMPINATY FTOTINAMED AND	IDADACETAMOL DADACETAMOL	Teen
EU-EC- 10013666978	05/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Fatigue (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
										Recovering/Resolving - ), Injection site pain (n/a -			
										Recovering/Resolving - ), Injection site reaction (n/a -			
										Recovering/Resolving - ), Scar pain (n/a - Recovering/Resolving			
EU-EC- 10013663037	04/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	- )  Cataract congenital (n/a - Not Recovered/Not Resolved - Disabling, Congenital Anomaly),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transplacental])	Not reported	ICSR
										Foetal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Disabling, Congenital Anomaly)			
EU-EC- 10013636400	30/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Foetal growth restriction (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC- 10013623159	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Exposure via breast milk (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
										Pyrexia (4d - Recovered/Resolved - )			
EU-EC- 10013625277	29/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013625306	29/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013613662	28/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Cardiac failure (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
										Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10013608236	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Febrile convulsion (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]),	Not reported	ICSR
										Product administration error (0d - Unknown - )	[ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALUMINIUM, HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED PRODUCED ON HUMAN DIPLOID (MRC-5) CELLS, ALGELDRATE,		
											HEPATITIS A VIRUS (INACTIVATED), HEPATITIS A VIRUS (INACTIVATED) ADSORBED ON ALUMINIUM HYDROXIDE HYDRATED, ALGELDRATE, HEPATITIS A VIRUS (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS ANTIGEN (INACTIVATED), HEPATITIS A VIRUS ANTIGEN, STRAIN HM175, INACTIVATED, ADSORBED ON ALUMINIUM HYDROXIDE, ALUMINIUM		

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											HYDROXIDE, HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), ALGELDRATE, HEPATITIS A VIRUS HM175 STRAIN (INACTIVATED), ALUMINIUM HYDROXIDE] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]),  [INFLUENZA A VIRUS		
											A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use])		
EU-EC- 10013597411	26/09/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Chills (1d - Recovered/Resolved - ), Lymphadenopathy (n/a - Recovering/Resolving - ), Pyrexia (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013579083	23/09/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Overdose (n/a - Unknown - ),  Product administered to patient of inappropriate age (n/a - Unknown - ),  Vaccination site pain (6h - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 5ug - Intramuscular use])	Not reported	ICSR
EU-EC- 10013573162	22/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Not Specified	Yes	Exposure via breast milk (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-		Spontaneous	Professional	Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),  Brief resolved unexplained event (n/a - Unknown - Caused/Prolonged Hospitalisation),  Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation), Other Medically Important Condition),  Gastrointestinal pain (n/a - Unknown - Other Medically Important Condition),  Infantile apnoea (n/a - Unknown - Other Medically Important Condition),  Laryngospasm (n/a - Unknown - Other Medically Important Condition),  Laryngospasm (n/a - Unknown - ),  Screaming (n/a - Unknown - ),  Screaming (n/a - Unknown - )  Haemangioma	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Transmammary])  COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10013542287	19/09/2022	Spontaneous	Professional		available	Month	(Preterm and Term newborns)	Female	No	Haemangioma congenital (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition)	COMIRNALY [10ZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Transplacental])	Not reported	<u>ICSR</u>
EU-EC- 10013542475	19/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Anal atresia (n/a - Fatal - Results in Death, Congenital Anomaly), Atrial septal defect (n/a - Fatal - Results in Death, Congenital Anomaly), Foetal death (n/a - Fatal - Results in Death), Generalised oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC- 10013520245	15/09/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Hypotonia (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	ICSR

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										Somnolence (1d - Recovered/Resolved - ),			
										Vomiting (1d - Recovered/Resolved - )			
EU-EC- 10013503082	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[DESOGESTREL] (C - Contraception - n/a - [n/a - 75ug - n/a])	ICSF
										), Frequent bowel movements (n/a - Recovering/Resolving - )			
EU-EC- 10013504219	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Atrial septal defect (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [197d - 3{DF} - Intraamniotic use])	Not reported	ICS
										Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly)			
EU-EC- 10013485105	12/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Infantile back arching (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	LEVETIRACETAM [LEVETIRACETAM] (C - Tuberous sclerosis complex - n/a - [1y - 400mg - Oral use])	ICSF
										Sleep terror (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10013458180	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10013436371	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC-	02/00/2022	Spontaneous	Non	Furancan	Not	2	Infant	Male	No	Recovered/Not Resolved - ) Diarrhoea (39d -	COMIRNATY [TOZINAMERAN]	Not reported	ICCI
10013414155	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	Months - 2 Years		Male	INO	Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular use])	Not reported	ICSF
EU-EC- 10013405304	01/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2	Not Specified	Male	No	Haematochezia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lactose intolerance (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]),  ROTARIX [HUMAN ROTAVIRUS RIX4414 STRAIN (LIVE ATTENUATED), HUMAN ROTAVIRUS RIX4414 STRAIN (LIVE ATTENUATED) PRODUCED ON VERO CELLS] (S - n/a - Not applicable -	Not reported	ICSR
											[n/a - n/a - n/a]),  [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN		
											(A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - n/a - Not applicable - [n/a - n/a - n/a]), [DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, HEPATITIS B SURFACE ANTIGEN (RDNA), PERTUSSIS		
											ANTIGEN (KIDNA, FERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN)] (S - n/a - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10013381539	30/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm	Male	Yes	Atrial septal defect (n/a - Not Recovered/Not		[LEVOTHYROXINE SODIUM] (C - Autoimmune thyroiditis - n/a - [n/a - 125ug - Transplacental])	ICS

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ESSC DATE Services Below Research State Record Medical Record Services Serv										during pregnancy (n/a - Unknown -				
## Wild Jack Company for Compa										Hypospadias (n/a - Not Recovered/Not Resolved - Congenital				
Received registation (Received and American Companied American)  Received and the companied of the companied and the companied of the companied and the comp										Mitral valve incompetence (n/a - Recovered/Resolved -				
U-4C   ACQUIRED Operationed   National State   Acquired   Acquir										Neonatal respiratory distress syndrome (n/a -				
BUHC:  Noting GD22 Sportmodes Militations  Professional Government Militations  Profe										Congenital Anomaly),				
25/66/2022   Sportsman,   Monthcase   Surviver   Marcol   Monthcase   Surviver   Month										pulmonary hypertension (n/a - Recovered/Resolved -				
Recovered Resolvable Compared Recovery 1, Small for calles being Recovered Recolvable Compared Recovery 1, Small for calles being Recovered Recolvable Recovered Recovered Recolvable Recovered Recolvable Recovered Recolvable Recovered Recolvable Recovered Recovered Recolvable Recovered Recovered Recovered Recolvable Recovered Recovered Recovered Recovered Recolvable Recovered Rec										arteriosus (n/a - Recovered/Resolved -				
El-EC-   10112599847   24,000,0002   Secretarionus Helefatraces   Suppose   Secretarionus Helefatraces   Secretarios   Sec										Recovered/Resolved -				
EU-CE   Mary   M										(n/a - Recovered/Resolved -				
hospitalisation), (IALIMPRUM HOSPINITE, Incided provided in the Commission of the Co			26/08/2022	Spontaneous	Economic		(Preterm and Term	Female	Yes	Foetal exposure during pregnancy (35d -	(S - COVID-19 immunisation - Not applicable - [1d3mL -	Not reported	ICSR	
restriction (ryla - Not Reconvending).  All matter (ryla - Not Reconvending).  Labil late (ryla - Not Reconvending).  Reconvending of the state o										Hospitalisation),	DIPHTHERIA TOXOID			
Cassed/Prolonged Hospitalisation Label to (ry's - Not Recovered/Rec Reco										restriction (n/a - Not Recovered/Not	HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE,			
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(n/a - Not.  Recovered/Not.  R										Hospitalisation),	PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM			
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Unknown - Caused/Protonged Hospitalisation)  Caused/Protonged Hospitalisation)  Hospitalisation)  Aliminum, pertrussis Toxiolio, Aliminum, pertrussis Pertrustis Pert										Caused/Prolonged Hospitalisation),	ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, ALGELDRATE,			
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											DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS (INACTIVATED) ADSORBED] (S - Immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])		
EU-EC- 10013331390	25/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Angioedema (92d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013322774	24/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Product administered at inappropriate site (n/a - Unknown - ), Pyrexia (9d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013309252	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	No	Asthenia (259d - Not Recovered/Not Resolved - ), Menstrual disorder (259d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous use])	Not reported	ICSR
EU-EC- 10013310417	23/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Poor quality product administered (n/a - Unknown - ), Product administration error (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	ICSR
EU-EC- 10013298659	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Feeling cold (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Myalgia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013299054		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	- 2 Years	Not Specified	Male	No	- Unknown - ),  Multisystem inflammatory syndrome in children (n/a - Unknown - Other Medically Important Condition),  Pyrexia (n/a - Recovered/Resolved - ),  Rash (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013287682	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Bradycardia foetal (1d - Recovered/Resolved - Life Threatening), Haemorrhage intracranial (161d - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC- 10013289403		Spontaneous	Healthcare Professional		Not available	- 2 Years	Not Specified	Female	No	Depressed mood (1d - Recovered/Resolved - ), Exposure via breast milk (n/a - Recovered/Resolved - ), Irritability (1d - Recovered/Resolved - ), Restlessness (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])		ICSR
EU-EC- 10013274796		Spontaneous	Healthcare Professional		Not available	- 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Recovered/Resolved - ),  Pyrexia (2d - Recovered/Resolved - ),  Vomiting (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])		ICSR
EU-EC- 10013276738		Spontaneous	Professional	Economic Area	Not available	- 2 Years	Not Specified	Not Specified		COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10013278264	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Amniotic cavity infection (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Transplacental])	Not reported	<u>ICSR</u>

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										Important Condition), Foetal growth restriction (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Foetal vascular malperfusion (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10013250709	16/08/2022	Spontaneous	Professional	European Economic Area	Not available		Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Flatulence (n/a - Unknown - ), Salivary			
										hypersecretion (n/a - Unknown - ), Sleep disorder (n/a -			
EU-EC- 10013256820	16/08/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Unknown - ) Chills (10d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (10d - Recovered/Resolved -			
										Hypotonia (10d - Recovered/Resolved - ),			
										Pyrexia (10d - Recovered/Resolved - )			
EU-EC- 10013229743	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	No	Eye movement disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
										Myoclonus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10013211690	10/08/2022	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Product administered at inappropriate site (n/a - Unknown - ),			
										Wheezing (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10013201423	09/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area			Not Specified	Female	Yes	Atrial septal defect (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
										Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10013168835	04/08/2022	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Cough (n/a - Recovering/Resolving - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
				Arca		lears				Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition),	арупеавте [та туа туа])		
										Dyspnoea (n/a - Unknown - ), Illness (n/a -			
										Recovering/Resolving - ),			
										Pneumonia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Respiratory distress (n/a - Unknown - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Recovering/Resolving -),			
										Suspected COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Wheezing (n/a - Recovering/Resolving - )			
EU-EC- 10013172435	04/08/2022	Spontaneous		Non European	Not available		Not Specified	Ma <b>i</b> e	No	Dyspnoea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>

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				Economic Area		- 2 Years				- Other Medically Important Condition)	Not applicable - [n/a - n/a - n/a])		
EU <b>-</b> EC- L0013154761	03/08/2022	Spontaneous		European Economic Area	Not available		Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
										Restlessness (n/a - Unknown - )	Transmammary])		
:U-EC- :0013154856	03/08/2022	Spontaneous		European	Not available	2 Months	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
10013154856			Healthcare Professional		avaliable	- 2 Years	Specified			), Pyrexia (n/a -	Not applicable - [1d - n/a - Transmammary])		
										Unknown - ), Restlessness (n/a -			
										Unknown - ), Tearfulness (n/a -			
EU-EC-	03/08/2022	Spontaneous		European	Not	2	Not	Female	No	Unknown - ) Off label use (n/a -	  COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10013159004			Healthcare Professional	Economic Area	available	Months - 2 Years	Specified			Unknown - ), Product use issue (n/a - Unknown - ),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Rash (n/a - Not Recovered/Not			
										Resolved - ), Urticaria (n/a - Not Recovered/Not			
	01/08/2022	Spontaneous		European	Not	0-1	Not	Not	Yes		COMIRNATY [TOZINAMERAN]	[LECITHIN] (C - n/a - n/a - )	ICSF
10013135803		,		Economic Area	available	Month	Specified	Specified		Unknown - ), Exposure via breast	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										milk (n/a - Unknown - ),			
										Infantile vomiting (n/a - Recovered/Resolved - ),			
										Restlessness (n/a - Unknown - ),			
										Screaming (n/a - Unknown - )			
EU-EC- 10013120599	29/07/2022	Spontaneous		European Economic Area	Not available	Months - 2	Adult	Female	No	Immunisation reaction (n/a - Recovered/Resolved -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSF
EU-EC- 10013123571	29/07/2022	Spontaneous		European Economic	Not available	Years 2 Months	Not Specified	Female	Yes	COVID-19 (n/a - Unknown - ),	- Intramuscular use])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF
10013123371			Professional	Area	avallable	- 2 Years	Specified			Exposure via breast milk (n/a - Unknown - ),	Not applicable - [n/a - n/a - Transmammary])		
										Infection (n/a - Unknown - ),			
										Otitis media (n/a - Unknown - )			
EU-EC- 10013102110	27/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Foetal exposure during pregnancy (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]),	Not reported	ICSF
										Jaundice (n/a - Unknown - )	[PERTUSSIS VACCINE] (S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10013091480	26/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Eye movement disorder (17d - Recovered/Resolved - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Hospitalisation), Off label use (n/a -			
										Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Product use issue (n/a - Unknown -			
										Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Seizure (17d - Recovered/Resolved -			
										Caused/Prolonged Hospitalisation, Other Medically Important			
EU-EC- 10013080461	25/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2	Infant	Not Specified	Yes	Condition)  Enanthema (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}} - Transplacentall)	Not reported	ICSF
						Years				Important Condition), Foetal exposure during pregnancy (0d - Unknown - Other	- Transplacental])		
										Medically Important Condition), Foetal exposure			
										during pregnancy (n/a - Unknown - Other Medically Important Condition),			
										Haematoma (n/a - Recovering/Resolving			

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										- Other Medically Important Condition), Petechiae (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10013084727	25/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Dyskinesia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSF
										Exposure via breast milk (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10013072606	22/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d2mL - n/a])	Not reported	ICSR
										Product administered at inappropriate site (n/a - Unknown - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10013053463	21/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Foetus	Not Specified	Yes	Adactyly (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transplacental])	Not reported	ICSR
										Infantile haemangioma (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly),			
										Maternal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly)			
EU-EC- 10013007911	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Haematochezia (15d - Not Recovered/Not Resolved - Other Medically Important Condition), Mucous stools (15d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10013013722	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	2 Months - 2	Adult	Female	No	Resolved - ) Hypotonia (13d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous use])	Not reported	ICSR
			FIOTESSIONAL	Area		Years				- ), Paraesthesia (13d - Recovering/Resolving - )	- II/a - Subcutaneous use])		
EU-EC- 10013013736	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Mobility decreased (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	ICSR
										Vaccination site joint pain (1d - Recovered/Resolved -			
EU-EC- 10012986275	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Foetal exposure during pregnancy (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]),	COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]),	ICSR
							·			Polydactyly (n/a - Unknown - Congenital Anomaly), Syndactyly (n/a -	FORMOTEROL, BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, BUDESONIDE,	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (C - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]),	
										Unknown - Congenital Anomaly)	FORMOTEROL FUMARATE HYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (S - Asthma - n/a - [n/a - n/a - Transplacental])	[MISOPROSTOL] (C - Labour induction - n/a - [n/a - n/a - Transplacental])	
EU-EC- 10012976419	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Limb reduction defect (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transplacental])	Not reported	ICSR
EU-EC- 10012980010	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported	ICSR
EU-EC- 10012957476	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Ear, nose and throat infection (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Off label use (n/a - Unknown - ),			

										Product use issue (n/a			
EU-EC-	08/07/2022	Spontaneous	Non	European	Not	2	Not	Male	Yes	- Unknown - ) Blister (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10012953750	,,			Economic	available		Specified			Recovered/Resolved - ),  Exposure via breast milk (n/a - Unknown -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])		
										Rash macular (n/a - Recovered/Resolved -			
EU-EC- 10012941942	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Myodonus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		[IBUPROFEN] (C - Abdominal pain - Drug withdrawn - [n/a - n/a - Transmammary]),  [PARACETAMOL] (C - Abdominal pain - Drug withdrawn - [n/a - n/a - Transmammary])	ICS
EU-EC- 10012929119	06/07/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Basedow's disease (n/a - Not Recovered/Not Resolved - Other Medically Important	Transmammary]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10012933296	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Condition)  Infantile spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Partial seizures (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Product administered to patient of inappropriate age (n/a - Unknown - )			
EU-EC- 10012909441	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Haematochezia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICS
EU-EC- 10012909446	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Haematemesis (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICS
EU-EC- 10012909822	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Maternal exposure during breast feeding (0d - Recovered/Resolved - ), Vomiting (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10012896742	01/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Female	Yes	Recovered/Resolved - )  Exposure via breast milk (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	Not reported	ICSI
										Pyrexia (n/a - Recovered/Resolved - )			
EU-EC- 10012905097	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Rectal haemorrhage (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Transmammary])	Not reported	ICSF
EU-EC- 10012905868	01/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Syndactyly (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [45d - 2{DF} - Intramuscular use])	Not reported	ICSF
EU-EC- 10012906942	01/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Poor feeding infant (6d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Transmammary])	Not reported	ICS
EU-EC- 10012882595	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal discomfort (299d - Recovered/Resolved With Sequelae - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Bone pain (299d - Recovered/Resolved With Sequelae - ), Diarrhoea (299d -			
										Recovered/Resolved With Sequelae - ), Dyspnoea (299d - Recovered/Resolved			
										With Sequelae - ), Feeling hot (299d - Recovered/Resolved			
EU-EC- 10012883790	30/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes	With Sequelae - ) Crying (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSF
							1.0.17001113)			Exposure via breast milk (n/a - Not Recovered/Not Resolved - ),			

										Insomnia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10012836291	24/06/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Unknown - ), Mucous stools (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012827061	23/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Neonate (Preterm and Term newborns)	Female	No	Unknown - )  Exposure via breast milk (n/a - Unknown - ),  Eye pruritus (n/a - Not Recovered/Not Resolved - ),  Eye swelling (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- 10012815735	22/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Restlessness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012815751	22/06/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Unknown - ),  Tachycardia (206d - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012789410	20/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes	Maternal exposure during breast feeding (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (21d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012789700	20/06/2022	Spontaneous		Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Hospitalisation)  Exposure via breast milk (n/a - Unknown - ),  Seizure (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012794575	20/06/2022	Spontaneous			Not available	2 Months - 2 Years	Not Specified	Female	No	Condition)  Exposure via breast milk (n/a - Not Recovered/Not Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012766917	17/06/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Resolved - ) Dermatitis atopic (n/a - Recovering/Resolving - ), Exposure via breast milk (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012726288	15/06/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Unknown - ),  Maternal exposure during breast feeding	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Other])	Not reported	ICSR
EU-EC- 10012729516	15/06/2022	Spontaneous		Non European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	(n/a - Unknown -) Cardiomyopathy neonatal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Congenital Anomaly)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental]),  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- 10012731442	15/06/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Developmental delay (n/a - Not Recovered/Not Resolved - Disabling), Hypotonia (n/a - Not Recovered/Not Resolved - Disabling), Maternal exposure during pregnancy (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICSR
EU-EC- 10012712451	14/06/2022	Spontaneous	Healthcare Professional	European Economic	Not available	0-1 Month	Neonate (Preterm	Female	Yes	- Unknown - Other Medically Important Condition) Atrial septal defect (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a		ICSR

				Area			and Term newborns)			Congenital Anomaly), Foetal arrhythmia (n/a - Recovered/Resolved - Congenital Anomaly), Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly), Patent ductus arteriosus (n/a - Unknown - Congenital Anomaly)	- n/a - Transplacental])	SODIUM S-LACTATE SOLUTION, LACTIC ACID, SODIUM SACTATE, LACTATE SOLUTION] (C - Product used for unknown indication - n/a - [n/a - n/a - Transplacental]),  [ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS TOXOID ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM PHOSPHATE, BORDETELLA PERTUSSIS FIMBRIAE TYPE 2 AND 3 ADSORBED ON ALUMINIUM PHOSPHATE, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FIRMBRIAL AGGLUTININGENS (FIM) 2 AND 3, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PROTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FIRMBRIAL AGGLUTININGENS (FIM) 2 AND 3, POLIOVIRUS (INACTIVATED) TYPE 1 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (PER-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (PER-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (POLIOVIRUS (INACTIVATED) TYPE 2 (POLIOVIRUS (INACTIVATED) TYPE 2 (POLIOVIRUS (INACTIVATED) TYPE 3 (PRODUCED IN VERO CELLS, POLIOVIRUS (PRODUCED IN VERO CELLS, POLIOVIRUS TYPE 2 (POLIOVIRUS TYPE 2 (POLIOVIRUS TYPE 2 (POLIOVIRUS TYPE 3) (C - Immunisation - n/a - [n/a - n/a - Transplacental]),	
EU-EC- 10012715062	06/2022	Spontaneous	Healthcare Professional			2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012716321	06/2022			Economic		0-1 Month	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012716322	06/2022			Economic	Not available	0-1 Month	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012704322	06/2022	Spontaneous			Not available	2 Months - 2 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - ),	TOZINAMERAN  [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										ine Listing Repor			
										Product use issue (n/a - Unknown - ),			
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012705367	13/06/2022	Spontaneous	Professional		Not available	0-1 Month	Not Specified	Female	Yes	Maternal exposure during pregnancy (n/a		PROGESTERONE, MICRONISED]	ICSR
				Area						Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly),	Not applicable - [1d - n/a - Transplacental])	(C - Prophylaxis - n/a - [47d - 200mg - n/a])	
										VACTERL syndrome (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly)			
EU-EC- 10012689161	10/06/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - )			
EU-EC- 10012693657		Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	White blood cell count decreased (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Transplacental])	·	ICSR
EU-EC- 10012682435	09/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	[ANHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]),	ICSR
										Menstruation irregular (n/a - Not Recovered/Not Resolved - ),	n/a])	[BUPRENORPHINE, NALOXONE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]),	
										Nausea (n/a - Not Recovered/Not Resolved - ),		[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a])	
										Oligomenorrhoea (n/a - Not Recovered/Not Resolved - ),			
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10012667670		Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Myalgia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10012667684	08/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - ), Oligomenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012667686	08/06/2022	Spontaneous	Healthcare	European Economic	Not available	0-1 Month	Not Specified	Ma <b>i</b> e	No	Resolved - ) Macular degeneration (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	PERINDOPRIL ARGININE] (C -	ICSR
			Professional	Area						Other Medically Important Condition), Visual impairment (n/a - Unknown -	Not applicable - [n/a - n/a - n/a])	n/a - Unknown - [n/a - n/a - n/a])	
EU-EC-	08/06/2022	Spontaneous	Healthcare	European	Not	0-1	Not	Ma <b>i</b> e	No	Other Medically Important Condition) Herpes zoster (n/a -	COMIRNATY [TOZINAMERAN]	PRADAXA [DABIGATRAN	ICSR
10012667687		·	Professional		available	Month	Specified			Recovered/Resolved - ), Injection site reaction	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]),	
										(n/a - Recovered/Resolved - )		[ALLOPURINOL] (C - n/a - Unknown - [n/a - n/a - n/a]),	
												Unknown - [n/a - n/a - n/a]), [ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]),	
EU EO	00/05/5			-						0.31.7.7	COMMUNITATION	[OLMESARTAN MEDOXOMIL] (C - n/a - Unknown - [n/a - n/a - n/a])	-
EU-EC- 10012667823	JUS/U6/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Resolved - Disabling), Feeling of body temperature change			
										(n/a - Not Recovered/Not Resolved - Disabling),			
										Headache (n/a - Not Recovered/Not Resolved - Disabling),			
	l				I			1		Hyperhidrosis (n/a -	l		

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										Not Recovered/Not Resolved - Disabling),			
										Myalgia (n/a - Not Recovered/Not Resolved - Disabling),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Disabling),			
										Sleep disorder (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10012667846	08/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Infertility female (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012669634	08/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Arthralgia (n/a - Not Recovered/Not Resolved - ),	n/a])		
										Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved - ),			
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Oligomenorrhoea (n/a - Not Recovered/Not Resolved - ),			
										Tremor (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10012671748	08/06/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Dyspnoea exertional (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	<u>ICSR</u>
										Fatigue (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Pulmonary embolism (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10012656636	07/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Infant	Female	No	Loss of consciousness (4d - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	ICSR
EU-EC-	07/06/2022	Spontaneous	Non	European	Not	2	Not	Male	No	Caused/Prolonged Hospitalisation) Abdominal pain (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012660840	, ,			Economic	available		Specified			Recovering/Resolving - ),  Vomiting projectile	(S - n/a - n/a - [n/a - n/a - Transmammary])		
EU-EC- 10012647040	06/06/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	(n/a - Unknown - )  Double outlet right ventricle (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Congenital Anomaly),			
										Fallot's tetralogy (n/a - Recovered/Resolved With Sequelae -			
EU-EC-	06/06/2022	Spontaneous	Healthcare	European	Not	0-1	Not	Not	No	Congenital Anomaly) Arthralgia (n/a -	   COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10012647207			Professional	Economic Area	available	Month	Specified	Specified		Unknown - ), Asthenia (n/a - Unknown - ), Chills (n/a - Unknown - ), Hyperhidrosis (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (24h - Recovered/Resolved - ), Vaccination site pain	(S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])		
EU-EC- 10012643151	04/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	- 2	Not Specified	Male	No	(n/a - Unknown - ) Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012620339	02/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Years  2 Months - 2 Years	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012624822	02/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Infant	Male	Yes	Resolved - )  Dry skin (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Exfoliative rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012600218	31/05/2022	Spontaneous	Healthcare Professional		Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Condition)  Body temperature increased (n/a - Recovered/Resolved - ),  Crying (n/a - Recovered/Resolved - ),  Exposure via breast milk (n/a - Unknown - ),  Restlessness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012592963	30/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved - ), Exposure via breast milk (n/a - Not Recovered/Not Resolved - ), Poor feeding infant (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012571531	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (46d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012574541	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Fatigue (1d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012574544	27/05/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Pyrexia (1d - Recovered/Resolved - ), Stomatitis (3d - Recovered/Resolved - )	(S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012575247	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

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										Eye infection (n/a - Recovered/Resolved -			
EU-EC- 10012576833	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Disease recurrence			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rhinorrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012562832	26/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Other])	Not reported	ICS
										C-reactive protein increased (n/a - Not Recovered/Not Resolved - ),			
										Lymphopenia (n/a - Not Recovered/Not Resolved - ),			
										Neutropenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012551265	25/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Exposure via breast milk (n/a - Unknown - ), Teething (n/a -			
EU-EC-	25/05/2022	Spontaneous	Healthcare	European	Not	2	Not	Not	Yes	Unknown - ) Exposure via breast	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10012551293			Professional					Specified		milk (n/a - Unknown - ), Poor feeding infant	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])		
EU-EC-		Spontaneous		European	Not	2	Infant	Female	No	(n/a - Unknown - ) Decreased appetite	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10012556144			Healthcare Professional	Economic Area	available	Months - 2 Years				(5d - Recovered/Resolved - ), Pyrexia (2d -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Oral])		
										Recovered/Resolved - ), Rash (7d -			
EU EC	22/05/2022	Constant	N	F	NI-A		T - 6 1	NA-1-	V	Recovered/Resolved - )	COMPONED STORY STORY SAMEDANIA	Natura esta d	Toca
EU-EC- 10012532626	23/05/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Pyrexia (n/a - Not Recovered/Not Resolved - ), Vomiting (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSF
EILEC	23/05/2022	Sponton and	Non	European	Not	2	Not	Female	No	Recovered/Resolved - ) Diarrhoea (1d -	COMIDNATY ITOZINAMEDANI	Not reported	TCC
EU-EC- 10012534952	23/05/2022	Spontaneous		European Economic Area	Not available		Specified	remale	No	Recovered/Resolved - ),  Exposure via breast	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										milk (n/a - Recovered/Resolved -			
EU-EC- 10012492606	18/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSF
										Malaise (n/a - Unknown - )			
EU-EC- 10012484725		Spontaneous	Professional	Area	Not available	0-1 Month	Not Specified	Male	Yes	Death neonatal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Transplacental])		ICSF
EU-EC- 10012484730		Spontaneous	Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Death neonatal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Transplacental])		ICSF
EU-EC- 10012485952		Spontaneous		European Economic Area	Not available		Not Specified	Female	Yes	Cough (n/a - Unknown - ), Exposure via breast	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	INOC reported	ICSF
										mijk (n/a - Unknown -			

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										), Infant irritability (n/a - Unknown - ), Infection (n/a - Unknown - ),			
										Rhinorrhoea (n/a -			
EU-EC- 10012472163	16/05/2022	Spontaneous		European Economic Area	Not available	2 Months	Infant	Ma <b>l</b> e	No	Unknown - )  Exposure via breast milk (40h - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min3mL	Not reported	ICSR
						Years				), Pyrexia (2d - Not Recovered/Not	- Other])		
										Resolved - ),  Pyrexia (40h - Recovered/Resolved -			
EU-EC- 10012473725	16/05/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Exposure via breast milk (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	16/05/2022	Spontaneous	Non	European	Not	0-1	Adult	Female	No	Pyrexia (2d - Recovered/Resolved - ) Dizziness (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012477353				Economic	available	Month				Recovering/Resolving - ),  Dyspnoea (n/a -	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		
										Recovering/Resolving - ), Influenza like illness			
EU-EC-	13/05/2022	Spontaneous	Non	European	Not	2	Not	Female	No	(n/a - Recovering/Resolving - ) Exposure via breast	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012459163	13/03/2022	Spontaneous		Economic	available		Specified	remale	INO	milk (n/a - Recovered/Resolved - ),	(S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	<u>ICSK</u>
EU-EC-	11/05/2022	Spontaneous	Non	European	Not	0-1	Adult	Female	No	Vomiting (0d - Recovered/Resolved - ) Anaphylactic shock	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012433972	11/03/2022	Spontaneous		Economic	available	Month	Addic	remale	No	(19d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	G- Immunisation - n/a - [n/a - n/a - n/a])	постеропеа	ICSIN
										Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012437055	11/05/2022	Spontaneous	Healthcare Professional		Not available	2 Months - 2 Years	Not Specified	Male	Yes	Gastrooesophageal reflux disease (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	<u>ICSR</u>
										Hypokinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012424208	10/05/2022	Spontaneous			Not available	2 Months - 2 Years	Infant	Not Specified	Yes	Glassy eyes (n/a - Recovered/Resolved - ), Maternal exposure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										during breast feeding (n/a - Unknown - ), Muscle spasms (n/a -			
										Recovered/Resolved - ), Screaming (n/a -			
										Recovered/Resolved -			
EU-EC- 10012424448	10/05/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Abdominal pain (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
										Nausea (3d - Recovered/Resolved - ),			
EU-EC-	09/05/2022	Spontaneous	Non	Non	Not	2	Not	Male	No	Vomiting (3d - Recovered/Resolved - ) Abdominal pain upper	COMIRNATY [TOZINAMERAN]	[NAPROXEN, NAPROXEN	ICSR
10012412074			Healthcare Professional	European	available		Specified			(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),		SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	
										Arthralgia (n/a - Not Recovered/Not			

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				Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Lethargy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
				Night sweats (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	
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										Unknown - ), Oropharyngeal pain (n/a - Not Recovered/Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important			
										Condition),  Product administered to patient of inappropriate age (n/a - Unknown - ),			
										Pruritus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Urticaria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Vaccination site hypoaesthesia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10012413216	09/05/2022	Spontaneous			Not available	0-1 Month	Adult	Female	No	Arrhythmia (17d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Chest pain (17d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Heart rate increased (17d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012405009	06/05/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	0-1 Month	Infant	Female	Yes	Dry skin (12d - Recovered/Resolved - ), Eczema (12d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
										), Exposure via breast milk (n/a - Unknown - ),			
										Skin exfoliation (12d - Recovered/Resolved - ),			
EU-EC-	05/05/2022	Spontaneous	Healthcare	European	Not	2	Infant	Female	No	Swelling (12d - Recovered/Resolved - ) Nipple exudate bloody	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10012389432 EU-EC-		Spontaneous	Professional	Economic Area	available Not	Months - 2 Years 2	Not	Female	No	(4d - Unknown - )  Erythema (1d -	(S - COVID-19 immunisation - n/a - [1d - 30ug - Intramuscular]) COMIRNATY [TOZINAMERAN]		ICSR
10012364431	,,,	, , , , , , , , , , , , , , , , , , , ,		Economic	available		Specified			Recovered/Resolved - ), Papule (1d -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved - ), Product administered to patient of			
										inappropriate age			

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										(n/a - Unknown - ), Pruritus (1d - Recovered/Resolved -			
EU-EC- 10012366853	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICS
EU-EC- 10012367159	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	_	Infant	Male	Yes	Epilepsy (26d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d3mL - Oral])	Not reported	ICS
										Maternal exposure during breast feeding (26d - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10012368673	03/05/2022	Spontaneous		European Economic Area	Not available	- 2	Not Specified	Male	No	Hospitalisation	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICS
						Years				Maternal exposure during breast feeding (n/a - Unknown - ), Pyrexia (8h -	n/a])		
EU-EC-	02/05/2022	Spontaneous	Healthcare	Non	Not	0-1	Not	Female	No	Recovered/Resolved - ) Fever neonatal (2d -	TOZINAMERAN	Not reported	ICS
10012356835	02/03/2022	Sportaneous			available		Specified	remaje	INO	Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	100
										Influenza like illness (2d - Recovered/Resolved - ),	<b>3</b>		
										Myalgia (2d - Recovered/Resolved - ),			
										Product administered to patient of inappropriate age (n/a - Unknown - )			
EU-EC- 10012350389	30/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2	Infant	Ma <b>i</b> e	No	Arthralgia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
						Years				Chills (n/a - Recovered/Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	30/04/2022	Spontaneous	Healthcare	European	Not	2	Child	Female	No	Pyrexia (n/a - Unknown - ) Lymphadenopathy	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10012350395	30,01,2022	Sportaneous	Professional		available	Months - 2 Years	Cilia	remale		(n/a - Not Recovered/Not Resolved - )	(S - n/a - n/a - [n/a - n/a - Intramuscular])	The reported	100
EU-EC- 10012346114	29/04/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (7d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Rash maculo-papular (7d - Recovering/Resolving -)			
EU-EC- 10012346605	29/04/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Male	No	Eczema (74d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Headache (74d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012324593	28/04/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Irritability (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
						icula				Listless (n/a - Recovering/Resolving - ),	, , , , , , , , , , , , , , , , , , ,		
										Maternal exposure during breast feeding (n/a - Unknown - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10012326056	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Abdominal pain (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Exposure via breast milk (n/a - Unknown - ),			
										Flatulence (2d - Recovered/Resolved -			

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EU-EC- 10012321084	27/04/2022	Spontaneous	Non Healthcare Professional	Economic		2 Months - 2 Years	Child	Female	No	No adverse event (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012302309	26/04/2022	Spontaneous	Healthcare Professional		Not available	2	Not Specified	Female	Yes	Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSF
EU-EC- 10012308766	26/04/2022	Spontaneous	Non Healthcare Professional		Not available	0-1 Month	Neonate (Preterm and Term newborns)	Female	No	-)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	MODERNA (CX-024414) [COVID- 19 MRNA VACCINE MODERNA (CX-024414)] (C - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	ICSF
EU-EC- 10012291882	25/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	Yes	milk (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Transmammary])	[LEVOTHYROXINE] (C - Hypothyroidism - n/a - [n/a - n/a - Transmammary])	ICSF
										Somnolence (n/a - Recovered/Resolved - )			
EU-EC- 10012297028	25/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Weight bearing difficulty (28d - Unknown - 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- 10012277531	22/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	-)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSI
EU-EC- 10012264174	21/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10012266109	21/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Foetus	Not Specified	Yes	Anomaly),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSI
										incompetence (n/a - Unknown - Congenital Anomaly)			
EU-EC- 10012269208	21/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain lower (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Asthenia (n/a - Not Recovered/Not Resolved - ),			
										Back pain (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not			
										Recovered/Not Resolved - ), Headache (n/a - Not			
										Recovered/Not Resolved - ),			
										Hypotonia (n/a - Not Recovered/Not Resolved - ),			
										Muscular weakness (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Neck pain (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10012257528	20/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Product administered to patient of inappropriate age (n/a - Unknown - ),			
										Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012260185	20/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Pain in jaw (n/a - Recovering/Resolving -)			
EU-EC-	13/04/2022	Spontaneous	Non	European	Not	0-1	Adult	Female	No	Bronchitis (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSF

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										Cardiac discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Cardiac failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10012185154	12/04/2022	Spontaneous		Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Infantile vomiting (n/a - Recovering/Resolving			
										- Other Medically Important Condition), Malaise (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012188041	12/04/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Abdominal distension (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
						rears				Abdominal pain (n/a - Recovering/Resolving - ),	intraniusculai j)		
										Regurgitation (n/a - Recovering/Resolving - )			
EU-EC- 10012160873	08/04/2022	Spontaneous	Healthcare Professional		Not available	2 Months - 2 Years	Not Specified	Female	Yes	Crying (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),			
										Frequent bowel movements (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Irritability (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Poor feeding infant (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Somnolence (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012147946	07/04/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012128125	06/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Urinary tract infection	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012130423	06/04/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Urinary tract infection (n/a - Unknown - ) Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
						Icuis				Fatigue (n/a - Not Recovered/Not	··· ~ 1)		

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									Resolved - ), Induration (n/a - Not Recovered/Not Resolved - ),			
									Myalgia (n/a - Not Recovered/Not Resolved - ),			
									Pain (n/a - Not Recovered/Not Resolved - ),			
									Skin disorder (n/a - Not Recovered/Not Resolved - ),			
									Urticaria (n/a - Not Recovered/Not Resolved - )			
05/04/2022	Spontaneous			Not available	2 Months - 2 Years	Infant	Male	No	Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
05/04/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Crying (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
									Diarrhoea (n/a - Recovering/Resolving - 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),			
									Somnolence (2d - Recovered/Resolved - Other Medically Important Condition)			
04/04/2022	Spontaneous	Healthcare		Not available	2 Months - 2 Years	Infant	Female	No	Febrile convulsion (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
04/04/2022	Spontaneous	Healthcare		Not available	0-1 Month	Infant	Female	No	Rash (n/a - Recovered/Resolved - )	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
01/04/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Anomaly, Other Medically Important Condition), Foetal exposure	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Transplacental]), [PROGESTERONE, MICRONISED] (S - Prophylaxis of abortion - n/a -	İHİNZIYLIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (HINI)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (HINI)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Immunisation - n/a - [n/a - n/a - Transplacental]), [ALUMINIUM PHOSPHATE,	ICSR
											DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, ALGELDRATE, ALUMINIUM PHOSPHATE, ALUMINIUM PHOSPHATE, ALUMINIUM PHOSPHATE, ALUMINIUM PHOSPHATE, ALUMINIUM, PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FERTACTIN, ALUMINIUM PHOSPHATE, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS	
	05/04/2022	05/04/2022 Spontaneous 05/04/2022 Spontaneous 04/04/2022 Spontaneous	05/04/2022 Spontaneous Healthcare Professional  05/04/2022 Spontaneous Non Healthcare Professional  04/04/2022 Spontaneous Non Healthcare Professional  04/04/2022 Spontaneous Non Healthcare Professional  04/04/2022 Spontaneous Healthcare Professional	05/04/2022 Spontaneous Healthcare Professional Sconomic Area  05/04/2022 Spontaneous Non Healthcare Professional Sconomic Area  04/04/2022 Spontaneous Non Healthcare Professional Sconomic Area  04/04/2022 Spontaneous Non Healthcare Professional Area  04/04/2022 Spontaneous Non Healthcare Professional Area  04/04/2022 Spontaneous Non Healthcare Professional Sconomic Area  04/04/2022 Spontaneous Healthcare Professional Economic Area	D5/04/2022 Spontaneous Healthcare Professional European Economic Area  Not available Area  D4/04/2022 Spontaneous Non Healthcare Professional Economic Area  Non Healthcare Professional European Economic Area  Not European Economic Area  Not available European Area  Not available European Area  Not available European Area  Not available European Area  Not available European Economic Area	D5/04/2022   Spontaneous   Healthcare   Professional   European   Not   2   Months - 2   Years	D5/04/2022   Spontaneous   Healthcare   Professional   European   Not available   Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Month Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Months Area   Month Area   Month Month Area   Month Month Area   Month Month Area   Month Month Area   Month Month Month Area   Month Mont	D5/04/2022   Spontaneous   Healthcare   Professional   Specified   Professional   D5/04/2022 Spontaneous Non Healthcare Professional Professional Professional Professional Specified Professional Professional Professional Specified Professional Professional Professional Specified Professional Pr	Resolved - ), Industrian (r)a - Not Recovered/Not Resolved - ), Phylagia (r)a - Not Recovered/Not Resolved - ), Phylagia (r)a - Not Recovered/Not Resolved - ), Phin (r)a - Not Recovered/Resolved - ), Phin (r)a - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered/Resolved - Not Recovered	Resolved - ), Industration (via - Not Recovered/Not Resolved - ), Industration (via - Not Recovered/Not Resolved - ), Pain (via - Not Recovered/Resolved - ), Pain (via	MONOCOZ   Spentaneous   New Years   Monocologo   Monoco	

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30.11.2022	03.09								Kun Li	ne Listing Repor	t	DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM HYDROXID, HYDRATED AND ALUMINIUM HOSPHATE, DIPHTHERIA TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, DIPHTHERIA TOXOID, TETANUS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, BORDETELLA PERTUSSIS (INACTIVATED) ADSORBED) (C - Immunisation - n/a - [n/a - n/a - Transplacental]),  [CYANOCOBALAMIN, VITAMIN B12] (C - Self-medication - n/a - [n/a - n/a - Transplacental]),  [FOLIC ACID] (C - Prophylaxis of neural tube defect - n/a - [n/a - 5mg - Transplacental]),  [FOLIC ACID] (C - Self-medication - n/a - [n/a - 17ansplacental]),  [VITAMIN D] (C - Self-medication - n/a - [n/a - 17ansplacental]),  [VITAMIN D] (C - Self-medication - n/a - [n/a - 17ansplacental]),	
EU-EC- 10012091136	01/04/2022	Spontaneous	Professional			Month	Neonate (Preterm and Term newborns)	Male	No	- Recovering/Resolving - Life Threatening, - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Foetal exposure during pregnancy (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
EU-EC- 10012070413			Healthcare Professional	Economic Area	available	Months - 2 Years	Not Specified	Male		Disabling)  Chills (n/a - Not Recovered/Not Resolved - ),  Fatigue (n/a - Not Recovered/Not Resolved - ),  Headache (n/a - Not Recovered/Not Resolved - ),  Migraine (n/a - Not Recovered/Not Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC- 10012071906	31/03/2022	Spontaneous		Economic	Not available	Month	Neonate (Preterm and Term newborns)	Not Specified	No	Exposure via breast milk (n/a - Unknown - ), Poor feeding infant (8d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Unknown])	nvot reported	<u>ICSR</u>
EU-EC- 10012078554	31/03/2022	Spontaneous	Professional		Not available	0-1 Month	Foetus	Not Specified	Yes	Congenital musculoskeletal disorder of limbs (n/a - Fatal - Results in Death, Congenital Anomaly, Other Medically Important Condition), Foetal exposure during pregnancy (n/a - Fatal - Results in Death, Congenital	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - n/a])	Not reported	ICSR

										Anomaly, Other Medically Important			
EU-EC- 10012062929	30/03/2022	Spontaneous		European Economic	Not available	2 Months	Not Specified	Male	No	Condition)  Exanthema subitum (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
			Professional	Alea		Years				Exposure via breast milk (n/a - Unknown -	Transmammary])		
EU-EC- L0012045044	29/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
EU-EC- 10012045181	29/03/2022	Spontaneous		Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Unknown - )  COVID-19 (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Confusional state (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Dizziness (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Facial paralysis (3d - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Heart rate increased (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Motor dysfunction (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Pain (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Palpitations (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Product administered at inappropriate site (n/a - Unknown - ),			
										Product administered to patient of inappropriate age (n/a - Unknown - ),			
										Pyrexia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
										Urticaria (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling)			
EU-EC- 10012045698	29/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No	Cardiac disorder (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
						lears				Chest discomfort (n/a - Unknown - ),			
										Joint swelling (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10012051276	29/03/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Male	No	Chills (n/a - Unknown - ), Headache (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Palpitations (n/a - Unknown - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10012030633	28/03/2022	Spontaneous		Non European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Cerebral disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	Not reported	ICS
										Convulsion in childhood (n/a - Unknown - Caused/Prolonged Hospitalisation, Other			

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										Medically Important Condition), Maternal exposure timing unspecified (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Neonatal seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10012031054	28/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Abnormal faeces (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012035984	28/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	Yes	Poor feeding infant (14d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
EU-EC- 10012036717	28/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Unknown - ), Exposure via breast milk (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10012040461	28/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Cerebral infarction (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly),			
										Porencephaly (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly)			
EU-EC- 10012012814	25/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Exposure via breast milk (n/a - Recovered/Resolved - ), Infantile vomiting (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011994747	24/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Female	No	- ) Asthenia (n/a - Unknown - ), Injection site pain (n/a - Unknown - ), Mixed anxiety and depressive disorder	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - ), Palpitations (n/a - Unknown - )			
EU-EC- 10011984160		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Chills (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011987763	23/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Asthenia (n/a - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Fatigue (n/a - Recovered/Resolved - ), Infant irritability (n/a -			
EU-EC- 10011987774	23/03/2022	Spontaneous	Healthcare Professional	European	Not available	0-1 Month	Not Specified	Not Specified	Yes	Recovered/Resolved - )  Exposure via breast milk (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
1001130///4			TOTESSIONAL	Area	avallable	HOURT	эресшей	specified		Moaning (n/a - Not Recovered/Not Resolved - ),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])		
										Neonatal disorder (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011987779	23/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Infant irritability (n/a - Recovered/Resolved - ),			

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										Somnolence (n/a -   Recovered/Resolved -  )			
EU-EC- 10011987809	23/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Infant irritability (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Resolved - ), Infantile vomiting (n/a - Not Recovered/Not Resolved - ),			
										Somnolence (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011945992	21/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Infantile vomiting (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
EU-EC-	21/03/2022	Spontaneous	Healthcare	European	Not	0-1	Not	Not	Yes	- Recovered/Resolved - ) Anxiety (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011946068	21/03/2022	Spontaneous	Professional		available	Month	Specified	Specified		Recovered/Resolved - ), Exposure via breast	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										milk (n/a - Unknown - ),			
										Infantile vomiting (n/a - Recovered/Resolved - ), Poor feeding infant			
										(n/a - Recovered/Resolved -			
EU-EC- 10011960245	21/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Congenital anomaly (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])	ICSF
										Congenital foot malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition),			
										Congenital musculoskeletal disorder of limbs (n/a - Not Recovered/Not Resolved - Congenital Anomaly, Other Medically Important Condition),			
EU EG	40/02/2022									Maternal exposure during pregnancy (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition)			1001
EU-EC- 10011929122	18/03/2022	Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Rash macular (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
EU-EC- 10011929132	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	- 2	Not Specified	Not Specified	Yes	Recovered/Resolved - ) Diarrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
						Years				Exposure via breast milk (n/a - Unknown -	Transmammary])		
EU-EC- 10011929519	18/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011929547	18/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Ma <b>l</b> e	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011931189	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2	Not Specified	Not Specified	Yes	Crying (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSF
										Exposure via breast milk (n/a - Unknown - ),  Infant irritability (n/a -			
										Recovered/Resolved - ), Sleep disorder (n/a - Recovered/Resolved -			
EU-EC- 10011931292	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Agitation (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
										Exposure via breast milk (n/a - Unknown -	Transmammary])		

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										), Increased appetite (n/a - Recovered/Resolved - ),			
										Irritability (n/a - Recovered/Resolved -			
EU-EC- 10011933762	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	- 2	Not Specified	Male	Yes	Abdominal pain upper (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
						Years				), Crying (n/a - Recovered/Resolved -	Transmammary])		
										Exposure via breast milk (n/a - Unknown - ),			
										Insomnia (n/a - Unknown - ),			
										Restlessness (n/a - Unknown - )			
EU-EC- 10011933845	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011933847	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSF
										Somnolence (n/a -   Recovered/Resolved -  )			
EU-EC- 10011934764	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abnormal faeces (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Crying (1d - Recovered/Resolved - ),			
										Exposure via breast milk (n/a - Unknown - ),			
										Flatulence (1d - Recovered/Resolved -			
EU-EC- 10011935133	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Faeces discoloured (n/a - Not Recovered/Not Resolved - )	7,5		
EU-EC- 10011935140	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Abdominal pain upper (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - ),			
										Infant irritability (n/a - Recovered/Resolved - ),			
										Tearfulness (n/a - Recovered/Resolved - )			
EU-EC- 10011935977	18/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Abnormal faeces (n/a - Recovered/Resolved - ), Diarrhoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Recovered/Resolved - ),  Exposure via breast			
EU-EC-	18/03/2022	Spontaneous	Healthcare	European	Not	0-1	Not	Female	Yes	milk (n/a - Unknown - ) Abdominal pain (n/a -	   COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011935984	10,03,2022	эропшпсоиз	Professional		available		Specified	Cinale	103	Recovered/Resolved - ), Crying (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	net reported	1001
										Recovered/Resolved - ), Diarrhoea (n/a -			
										Recovered/Resolved - ), Discomfort (n/a - Recovered/Resolved -			
										), Exposure via breast milk (n/a - Unknown -			
EU-EC- 10011922250	17/03/2022	Spontaneous	Healthcare Professional		Not available		Not Specified	Not Specified	Yes	Abnormal faeces (2d - Recovered/Resolved -	(S - COVID-19 immunisation -	Not reported	ICSR
,				Area		- 2 Years				),	Not applicable - [1d - n/a - Transmammary])		

										Frequent bowel movements (2d - Recovered/Resolved -			
EU-EC- 10011922459		Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Cerebral haemorrhage neonatal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transplacental])	Not reported	ICSR
										Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Foetal exposure timing unspecified (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Inappropriate antidiuretic hormone secretion (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Posthaemorrhagic hydrocephalus (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)			
EU-EC- 10011922814		Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Diarrhoea (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
						rears				Exposure via breast milk (n/a - Unknown - ),	Transmarry)		
										Irritability (n/a - Recovered/Resolved - )			
EU-EC- 10011922818		Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Body temperature increased (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC-	17/03/2022	Spontaneous	Healthcare	European	Not	2	Not	Not	Yes	Exposure via breast milk (n/a - Unknown - ) Exposure via breast	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011922832	17/03/2022	Sportaneous	Professional	Economic Area			Specified	Specified	ies	milk (n/a - Unknown - ),  Infantile vomiting (n/a - Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	not reported	ICSIX
EU-EC- 10011922837	17/03/2022	Spontaneous	Professional	European Economic Area	Not available	- 2	Not Specified	Not Specified	Yes	Anxiety (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
						Years				Body temperature increased (n/a - Recovered/Resolved - ),	Transmammary])		
										Exposure via breast milk (n/a - Unknown - ),			
										Somnolence (n/a - Recovered/Resolved -			
EU-EC- 10011923172		Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<u>ICSR</u>
						, 54.5				Poor feeding infant (n/a - Recovered/Resolved -	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
EU-EC- 10011924087	17/03/2022	Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Apathy (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - ),			
										Somnolence (n/a - Recovered/Resolved - ),			
										Tearfulness (n/a - Recovered/Resolved - )			
EU-EC- 10011924092		Spontaneous	Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR

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										Poor feeding infant (n/a - Recovered/Resolved - ),			
										Restlessness (n/a - Recovered/Resolved - ),			
										Tension (n/a - Recovered/Resolved -			
EU-EC- 10011924095	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011924445	17/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Laryngitis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Oral])	Not reported	ICSR
EU-EC- 10011925721	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2	Not Specified	Not Specified	Yes	Abdominal pain (1d - Recovered/Resolved - ), Exposure via breast	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011925759	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	milk (n/a - Unknown - )  Body temperature increased (n/a - Recovered/Resolved - ),  Exposure via breast	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011926070	17/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	milk (n/a - Unknown - )  Exposure via breast milk (n/a - Unknown - ),  Frequent bowel movements (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011905489	16/03/2022	Spontaneous		European Economic Area	Not available	2 Months	Not Specified	Male	No	Recovered/Resolved - )  Vaccination site reaction (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011905511	16/03/2022	Spontaneous		European Economic	Not available	Years 2 Months - 2	Child	Male	No	Injection site erythema (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011905513	16/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Years  2  Months - 2  Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011905518	16/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011907019	16/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	[IBUPROFEN, IBUPROFEN LYSINE, IBUPROFEN PH. EUR., IBUPROFEN SODIUM, IBUPROFEN SODIUM DIHYDRATE] (C - Pyrexia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10011911712	16/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Not Specified	Yes	Perinatal stroke (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]),	Not reported	ICSR
										Pulmonary arterial hypertension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	[PAROXETINE MESILATE] (S - COVID-19 immunisation - n/a - [n/a - 10mg - Transplacental])		
EU-EC- 10011912731	16/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Exposure via breast milk (n/a - Unknown - ), Vomiting (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011890850	15/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Not Specified	Male	No	Recovered/Resolved - )  Rash (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011894769	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years  2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
						rcurs				Pyrexia (72h - Unknown - ), Rash (72h - Unknown - ),	Transmanniary))		
EU-EC- 10011895085	15/03/2022	Spontaneous	Healthcare Professional	European Economic	Not available	2 Months	Not Specified	Not Specified	Yes	Roseola (72h - Unknown - ) Exposure via breast milk (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			sectorial	Area		- 2 Years	- Serveu			), Pyrexia (2d - Recovered/Resolved - ),	Not applicable - [1d - n/a - Transmammary])		
EU-EC- 10011895086	15/03/2022	Spontaneous	Healthcare Professional		Not available		Not Specified	Not Specified	Yes	Viral infection (n/a - Unknown - ) Exposure via breast milk (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - III d - N/3 -	Not reported	ICSR
				Area		- 2 Years				Ocular hyperaemia	Not applicable - [1d - n/a - Transmammary])		

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										(n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Rhinorrhoea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011895396	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Cough (n/a - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Rhinorrhoea (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011895402	15/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Rash (n/a - Not Recovered/Not Resolved - ), Skin disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011897860	15/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Asthenia (n/a - Recovered/Resolved - ), Cough (n/a - Recovered/Resolved - ), Exposure via breast milk (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Rhinorrhoea (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011875242	14/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Infection (n/a - Unknown - ), Product administered at inappropriate site (n/a - Unknown - ), Product administered to patient of inappropriate age (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Product use issue (n/a - Unknown - ), Pyrexia (5d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011876250		Spontaneous	Healthcare Professional			2 Months - 2 Years		Female	No	- Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011877343	14/03/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition), Haematochezia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011878086	14/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011884018		Spontaneous	Healthcare Professional			2 Months - 2 Years		Male	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	·	<u>ICSR</u>
EU-EC- 10011884142		Spontaneous Spontaneous	Healthcare Professional		Not available Not	2 Months - 2 Years	Infant	Male Male	No No	Exposure via breast milk (n/a - Unknown - ), Vomiting (n/a - Unknown - ) Cold sweat (2d -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN]		ICSR ICSR
10011874430	1.5/05/2022	Spontaneous		European Economic Area			Not Specified	I <sup>M</sup> Idle	INU	Cold sweat (2d - Recovered/Resolved - ), Exposure via breast mlk (n/a - Recovered/Resolved - ), Insomnia (2d - Recovered/Resolved -	COMIRNATY   TOZINAMERANJ (S - Immunisation - n/a - [n/a - n/a - Transmammary])	постеропец	<u>ICSK</u>

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EU-EC- 10011856194	11/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Recovered/Resolved - )  Asthma (n/a - Unknown - ),  Crying (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Transmammary])	[DESOGESTREL] (C - Contraception - n/a - [n/a - n/a - Transmammary])	ICS
										Crying (n/a - Unknown - ), Discomfort (2d - Recovered/Resolved -			
										Discomfort (n/a - Unknown - ),			
										Exposure via breast milk (n/a - Unknown - ),			
										Initial insomnia (2d - Recovered/Resolved - ),			
										Initial insomnia (n/a - Unknown - ),			
										Pain (2d - Recovered/Resolved - ),			
										Pain (n/a - Unknown - ),			
										Restlessness (2d - Recovered/Resolved - )			
EU-EC- 10011843148	10/03/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Occupational exposure to product (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011848931	10/03/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Child	Female	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011849371	10/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	Years 0-1 Month	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICS
										Fever neonatal (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011816769	08/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Dry skin (n/a - Recovering/Resolving -), Erythema (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Transmammary])	Not reported	ICS
										Recovering/Resolving - ), Skin lesion (n/a - Recovering/Resolving			
EU-EC- 10011804903	07/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Exposure via breast milk (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Periorbital oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011811933	07/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Diarrhoea (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Other])	Not reported	ICS
EU-EC- 10011797125	04/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	0-1	Not Specified	Not Specified	Yes	Death neonatal (n/a - Fatal - Results in Death), Maternal exposure	COMENTATY [TOZINAMERAN] (S - Product used for unknown indication - Not applicable - [n/a - n/a - Transplacental]),	Not reported	ICS
										during pregnancy (n/a - Unknown - ), Premature baby (n/a - Unknown - Other Medically Important Condition)	KEPPRA [LEVETIRACETAM] (S - Product used for unknown		
EU-EC- 10011798099	04/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	Yes	Exposure via breast milk (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Transmammary])	Not reported	ICS
										Vomiting (2d - Recovered/Resolved -			

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EU-EC- 10011779584	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site pain (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011780389	03/03/2022	Spontaneous		European Economic	Not available	0-1 Month	Adult	Female	No	Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Limb discomfort (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Tachycardia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011782596	03/03/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Congenital hand malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Transplacental])	Not reported	ICSR
										Kidney malformation (n/a - Not Recovered/Not Resolved - Congenital Anomaly),			
										Small for dates baby (n/a - Not Recovered/Not Resolved - Congenital Anomaly),			
										Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital			
EU-EC- 10011784354	03/03/2022	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adult	Female	No	Anomaly)  Arthralgia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
										Limb discomfort (n/a - Recovering/Resolving - ),			
										Pain in extremity (n/a - Recovering/Resolving			
EU-EC- 10011784363	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	- ) Epistaxis (9d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not	Not reported	ICSR
										Influenza like illness (9d - Not Recovered/Not Resolved - ),	otherwise specified)])		
										Lymphadenopathy (9d - Not Recovered/Not Resolved - )			
EU-EC- 10011784368	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza like illness (30d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Injection site pain (30d - Not Recovered/Not Resolved - )			
EU-EC- 10011784415	03/03/2022	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
										Paraesthesia (n/a - Not Recovered/Not Resolved - ),			
										Sensory disturbance (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011784512	03/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	<del>'</del>	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011784517	03/03/2022	Spontaneous		European Economic	Not available	0-1 Month	Adult	Female	No	Neuralgia (2d - Recovered/Resolved With Sequelae - ), Paraesthesia (2d -	i	Not reported	ICSR
EU-EC-	03/03/2022	Spontaneous	Non	European	Not	0-1	Adult	Male	No	Recovered/Resolved With Sequelae - ) Influenza like illness	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011784630	33, 33, 2022	Sporturicous	Healthcare Professional	Economic		Month	, wate	, idic		(n/a - Unknown - ),	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])	, reported	2001

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										Local reaction (n/a - Unknown - ), Vaccination site reaction (n/a -			
EU-EC- 10011784643	03/03/2022	Spontaneous	Healthcare	European Economic	Not available	0-1 Month	Adult	Female	No	Unknown - ) Chills (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional	Area						Headache (5d - Recovering/Resolving	- n/a - Intramuscular])		
										Movement disorder			
										Recovered/Resolved - ), Pyrexia (3d -			
EU-EC- 10011784691	03/03/2022	Spontaneous	Non Healthcare	European Economic	Not available	0-1 Month	Adult	Female	No	Recovering/Resolving -) Injection site joint pain (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional							Recovering/Resolving - ),	- n/a - Subcutaneous])		
EU-EC-	03/03/2022	Spontaneous	Non	European	Not	0-1	Adult	Female	No	Limb discomfort (n/a - Recovering/Resolving - ) Arthralgia (208d - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011784709	03/03/2022	Spontaneous		Economic	available	Month	Addit	remaje		Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [n/a - n/a - Subcutaneous])	Not reported	<u>ICSN</u>
										Myalgia (208d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011774085	02/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (89d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011743341	01/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2	Not Specified	Female	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
EU-EC- 10011749012	01/03/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2	Not Specified	Male	No	Exposure to SARS- CoV-2 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
				/ II Cu		rears				Off label use (n/a - Unknown - ),	apprease [ive ive ive])		
EU-EC-	01/03/2022	Spontaneous	Non	European	Not	0-1	Neonate	Female	Yes	Product use issue (n/a - Unknown - ) Abnormal faeces (n/a	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011749179		·		Economic	available	Month	(Preterm and Term newborns)			Recovering/Resolving	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	·	
										Exposure via breast milk (n/a - Unknown - )			
EU-EC- 10011751399	01/03/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Infant	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Oral])	Not reported	ICSR
EU-EC- 10011752975	01/03/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Male	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011753206	01/03/2022	Spontaneous			Not available	0-1 Month	Adult	Female	No	Injection site pain (3d - Recovered/Resolved - )	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011729965	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Drug interaction (n/a - Unknown - ),  Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (I - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Immune-mediated adverse reaction (n/a - Unknown - )			
EU-EC- 10011734014	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Male	No	Dyspnoea (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Respiratory distress (n/a - Recovering/Resolving -),			
										Sleep disorder (n/a - Recovering/Resolving - )			
EU-EC- 10011734015	28/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Asthenia (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Breast pain (3d - Recovered/Resolved - ),			
										Fatigue (3d - Recovered/Resolved - ), Vaccination site pain			
										(3d - Recovered/Resolved -			

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EU-EC- 10011738130	28/02/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	0-1 Month	Infant	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Transmammary])	Not reported	ICSR
										Somnolence (n/a - Not Recovered/Not			
EU-EC-	28/02/2022	Spontaneous	Non	European	Not	2	Infant	Male	No	Resolved - ) Pityriasis rosea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011742390		·	Healthcare Professional	Economic Area	available	Months - 2				Recovering/Resolving - )	(S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10011705318	24/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Years 2 Months - 2	Infant	Male	Yes	Crying (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL -	Not reported	ICSR
						Years				Decreased appetite (n/a - Recovered/Resolved -	Transmammary])		
										), Diarrhoea (1d - Recovered/Resolved -			
										), Exposure via breast milk (n/a - Unknown -			
										), Pain (1d - Recovered/Resolved -			
										), Pyrexia (1d - Recovered/Resolved -			
EU-EC- 10011692653	23/02/2022	Spontaneous	Healthcare Professional	Non European	Not available	2 Months	Not Specified	Female	Yes	Dyspnoea (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-	CANNABIDIOL [CANNABIDIOL] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
				Economic Area		- 2 Years				Lethargy (n/a - Unknown - Caused/Prolonged	19 immunisation - Not applicable - [1d - n/a - Transplacental])	[ACICLOVIR, ACICLOVIR SODIUM] (C - n/a - n/a - [n/a - 400mg - Transplacental]),	
										Hospitalisation),  Maternal exposure during pregnancy (n/a - Unknown - Caused/Prolonged Hospitalisation),		[ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a -	
										White blood cell count increased (n/a - Unknown - Other Medically Important Condition)		2{DF} - Transplacental]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - 400mg - Transplacental]),	
												[BIOTIN] (C - n/a - n/a - [n/a - 500ug - Transplacental]),	
												[BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [n/a - 300mg - n/a]),	
												[CAFFEINE] (C - n/a - n/a - [n/a - 600mg - n/a]),	
												[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Transplacental]),	
												[CHLORPHENAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, IBUPROFEN, IBUPROFEN] (C - n/a - n/a - [n/a - 600mg - n/a]),	
												[COLECALCIFEROL] (C - n/a - n/a - [n/a - 2{DF} - Transplacental]),	
												[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Transplacental]),	
												[CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1000ug - Transplacental]),	
												[FOLIC ACID] (C - n/a - n/a - [n/a - n/a - Transplacental]),	
												[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Transplacental]),	
												[PYRIDOXINE HYDROCHLORIDE, VITAMIN B6] (C - n/a - n/a - [n/a - 2mg - Transplacental]),	
												[RIZATRIPTAN, RIZATRIPTAN BENZOATE] (C - n/a - n/a - [n/a - 10mg - Transplacental]),	
												[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - n/a]),	
												[SUMATRIPTAN, SUMATRIPTAN SUCCINATE] (C - n/a - n/a - [n/a - 100mg - Transplacental]),	
												[VITAMIN D] (C - n/a - n/a - [n/a - n/a - Transplacental])	
EU-EC- 10011698108	23/02/2022	Spontaneous	Healthcare Professional		Not available	0-1 Month	Not Specified	Female	Yes	Epileptic encephalopathy (n/a - Unknown - Disabling,	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - n/a])	ICSR

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				Economic Area						Other Medically Important Condition),	applicable - [1d - n/a - Transplacental])		
										Maternal exposure during pregnancy (n/a - Unknown - Other Medically Important Condition),			
										Neonatal epileptic seizure (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Neonatal seizure (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition)			
EU-EC- 10011685747	22/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Musculoskeletal pain (2d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011685770	22/02/2022	Spontaneous			Not available	2 Months - 2 Years	Adult	Male	No	Asthenia (3d - Not Recovered/Not Resolved - ), Chills (3d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
										Recovered/Not Resolved - ), Headache (3d - Not Recovered/Not			
										Resolved - ), Limb discomfort (3d - Not Recovered/Not Resolved - )			
EU-EC- 10011664970	21/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Congenital Anomaly),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
										Foetal exposure during pregnancy (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Congenital Anomaly),			
EU EG	24 (22 /2022		Harlibarra		No		Newstand	M-I	Was	Hemiplegia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Congenital Anomaly)			LCCD
EU-EC- 10011667174	21/02/2022	Spontaneous	Professional	European Economic Area	Not available	0-1 Month	Neonate (Preterm and Term newborns)	Male	Yes	Aneurysm (n/a - Recovered/Resolved - Congenital Anomaly), Thrombosis (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Recovered/Resolved - Congenital Anomaly), Vena cava thrombosis (n/a -			
EU-EC-	21/02/2022	Spontaneous	Non	European	Not	0-1	Adult	Female	No	Recovered/Resolved - Congenital Anomaly) Abdominal pain (11d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011667588	21,02,2022	Spontaneous		Economic	available	Month	, addic	- Cinale		Recovered/Resolved - ), Dizziness (11d - Recovered/Resolved -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	The reported	10011
										), Fatigue (11d - Recovered/Resolved - ),			
										Headache (11d - Recovered/Resolved - ),			
										Muscular weakness (11d - Recovered/Resolved - ),			
										Pain in extremity (11d - Recovered/Resolved - )			
EU-EC- 10011651825	18/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Infant	Female	Yes	Nasopharyngitis (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
EU-EC- 10011635425	17/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Child	Female	Yes	Exposure via breast milk (n/a - Unknown - ),	Unknown - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF})	Not reported	ICSR
						Years				Fatigue (3d - Recovered/Resolved - ),	- Transmammary])		
										Somnolence (3d - Recovered/Resolved - ),			
•		•									•	•	, 1

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										Tearfulness (3d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011635645	17/02/2022	Spontaneous		Economic	Not available	2 Months - 2 Years	Elderly	Male	No	Influenza (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011635782	17/02/2022	Spontaneous		European Economic Area	Not available		Elderly	Female	No	Arrhythmia (6d - Recovering/Resolving - ), Back pain (6d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										- ), Burning sensation (6d - Recovering/Resolving			
										- ), Diarrhoea (6d - Recovering/Resolving - ),			
										Gastrointestinal pain (6d - Recovering/Resolving -),			
										Myalgia (6d - Recovering/Resolving - ),			
										Nausea (6d - Recovering/Resolving - ), Peripheral vascular			
EU-EC-	17/02/2022	Spontaneous	Non	Non	Not	2	Not	Male	No	disorder (6d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011635999	17/02/2022	Spontaneous	Healthcare Professional	European	available		Specified	Male	NO	(n/a - Recovering/Resolving - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSK</u>
										Eye pain (2880min - Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011641330	17/02/2022	Spontaneous	Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Overdose (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Product administered at inappropriate site (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Product administered to patient of inappropriate age (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10011643768	17/02/2022	Spontaneous	Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	No	Overdose (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Product administered at inappropriate site (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Product administered to patient of inappropriate age (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Life			

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EU-EC-	16/02/2022	Spontaneous	Non	European	Not	2	Child	Female	No	Hospitalisation)  Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011621560		,	Healthcare Professional	Economic	available	Months - 2 Years				Recovered/Not Resolved - )	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011621665	16/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011621708	16/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Child	Male	No	Dizziness (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
						Years				Injection site pain (1d - Recovered/Resolved - )			
EU-EC- 10011622383	16/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site erythema (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Injection site swelling (2d - Recovered/Resolved -			
EU-EC- 10011629246	16/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Cellulitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
										Impaired healing (n/a			
										Recovering/Resolving - Other Medically Important Condition),			
										Tenosynovitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011595836	14/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Male	Yes	Aplasia cutis congenita (n/a - Unknown - Congenital Anomaly, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - n/a - Transplacental]),	ICSF
										Foetal exposure during pregnancy (n/a - Unknown - Congenital Anomaly)		[SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Transplacental]),	
EU-EC-	14/02/2022	Spontaneous	Healthcare	European	Not	2	Not	Not	No	Decreased appetite	COMIRNATY [TOZINAMERAN]	[VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - Transplacental]) Not reported	ICSF
10011600779			Professional	Economic Area	available	Months - 2 Years	Specified	Specified		(n/a - Unknown - ), Exposure via breast milk (n/a - Unknown - ),	(S - COVID-19 immunisation - Not applicable - [n/a3mL - Transmammary])		
										Food refusal (n/a - Unknown - ),			
										Infant irritability (n/a - Unknown - ),			
EU-EC-	14/02/2022	Cnontonoous	Llaalthaava	Furancan	Not	2	Not	Not	No	Restlessness (n/a - Unknown - )	COMPONATY FTOZINAMEDANI	Not reported	ICCI
10011600821	14/02/2022	Spontaneous		European Economic Area	Not available		Not Specified	Not Specified	No	Exposure via breast milk (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Transmammary])	Not reported	ICSF
EU-EC- 10011602708	14/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Cough (n/a - Unknown - ), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Transmammary])	Not reported	ICSR
						lears				(n/a - Unknown - ), Exposure via breast	Transmaninary))		
										milk (n/a - Unknown - ), Fatigue (n/a -			
										Unknown - ), Infant irritability (n/a - Unknown - ),			
										Mucosal discolouration (n/a - Unknown - ),			
										Ocular hyperaemia (n/a - Unknown - ),			
										Pyrexia (n/a - Recovered/Resolved -			
EU-EC- 10011604695	14/02/2022	Spontaneous	Professional	European Economic Area	Not available	0-1 Month	Infant	Female	No	Maternal exposure during breast feeding (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Transmammary])	Not reported	ICSF
										Pyrexia (4d - Recovered/Resolved -			
EU-EC- 10011592251	13/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Child	Female	No	Injection site pain (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011592268	13/02/2022	Spontaneous		European Economic	Not available	Years 2 Months	Child	Male	No	Pyrexia (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF

			Professional	Area		- 2 Years				), Rash (3d -	- n/a - n/a])		
EU-EC- 10011592354	13/02/2022	Spontaneous	Healthcare	European Economic	Not available	0-1 Month	Adult	Female	No	Recovered/Resolved - ) Influenza (2d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a		ICS
			Professional	Area						Resolved - ), Pruritus (2d - Not Recovered/Not	- n/a - n/a])		
										Resolved - ), Swelling (2d - Not Recovered/Not			
EU-EC- 10011589690	12/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Child	Male	No	Resolved - )  No adverse event (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICS
EU-EC- 10011589950	12/02/2022	Spontaneous		European Economic Area	Not available	Years 0-1 Month	Adult	Female	No	Lymphoedema (161d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICS
EU-EC- 10011557762	10/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Infant	Female	No	Hospitalisation)   Cough (6d -   Recovered/Resolved -  ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICS
										Dyspnoea (6d - Recovered/Resolved - ),			
										Frequent bowel movements (6d - Recovered/Resolved - ),			
										Influenza (6d - Recovered/Resolved - ),			
										Salivary hypersecretion (6d - Recovered/Resolved -			
										Vomiting (6d - Recovered/Resolved -			
EU-EC- 10011557787	10/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Fatigue (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICS
						, cars				General physical health deterioration (2d - Recovering/Resolving			
										- ), Injection site pain (2d - Recovered/Resolved			
										Malaise (2d - Recovering/Resolving			
										Vaccination site pain (2d - Recovered/Resolved -			
EU-EC- 10011557995	10/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Child	Male	No	Malaise (2d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		<u>ICS</u>
						Years				Rash (2d - Not Recovered/Not Resolved - )	, , , ,		
EU-EC- 10011558013	10/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		<u>ICS</u>
EU-EC- 10011558033	10/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICS
EU-EC- 10011558184	10/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal discomfort (38d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICS
										Abnormal faeces (38d - Not Recovered/Not Resolved - )			
EU-EC- 10011558308	10/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Malaise (0d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		<u>ICS</u>
EU-EC-	10/02/2022	Spontaneous	Non	European	Not	2	Child	Male	No	Pyrexia (0d - Recovering/Resolving - ) Fatigue (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011558311				Economic	available	Months - 2 Years				Recovered/Resolved - ), Malaise (3d -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
i i										Recovered/Resolved -			
										), Mood altered (3d - Recovered/Resolved -			

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					- 2 Years				Rash vesicular (n/a - Not Recovered/Not Resolved - )			
10/02/2022	Spontaneous	Healthcare		Not available	0-1 Month	Adult	Female	No	Cough (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
									Influenza (n/a - Not Recovered/Not Resolved - ),			
									Nasopharyngitis (n/a - Not Recovered/Not Resolved - ),			
									Palpitations (n/a - Not Recovered/Not Resolved - ),			
10/02/2022	Spontaneous	Non	Furonean	Not	2	Not	Male	No	Tachycardia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
		Healthcare Professional	Economic Area	available	Months - 2 Years	Specified			Recovered/Resolved -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
10/02/2022	Spontaneous	Healthcare	Economic	Not available	Months - 2		Male	No	Fatigue (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
									Injection site pain (2d - Recovered/Resolved - ),			
									Vaccination site pain (2d - Recovered/Resolved -			
10/02/2022	Spontaneous	Healthcare		Not available		Adult	Male	No	Myalgia (22d - Recovered/Resolved -	(S - Immunisation - n/a - [n/a	Not reported	ICSR
10/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	Years 2 Months	Not Specified	Male	No	No adverse event (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
10/02/2022	Spontaneous	Non	European	Not	Years 2	Infant	Male	No	Body temperature	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				avaliable	- 2 Years				Recovering/Resolving - ),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
									Diarrhoea (n/a - Recovering/Resolving - ),			
									Dyspnoea (n/a - Recovering/Resolving - ),			
									Faeces discoloured (n/a - Recovering/Resolving			
									Vomiting (n/a - Recovering/Resolving			
10/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Not Specified	Female	Yes	Atrial septal defect (n/a - Not Recovered/Not Resolved - Congenital	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular]),	Not reported	ICSR
									Ventricular septal defect (n/a - Not Recovered/Not Resolved - Congenital	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		
10/02/2022	Spontaneous	Healthcare		Not available		Infant	Female	No	Cough (15d - Recovered/Resolved -	(S - Immunisation - n/a - [n/a	Not reported	ICSR
		rioressional	Aled		Years				Fatigue (15d - Recovered/Resolved -	iya iyaji		
									Influenza like illness (15d - Recovered/Resolved -			
									Pyrexia (15d - Recovered/Resolved -			
									Rash (15d - Recovered/Resolved -			
									Subglottic laryngitis (15d -			
10/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2	Elderly	Ma <b>l</b> e	No	Vaccination site reaction (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
10/02/2022	Spontaneous	Healthcare	European Economic	Not available	Years 2 Months - 2	Not Specified	Not Specified	Yes	Crying (20min - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Transmammary])	Not reported	ICSR
		Professional	Area					1				
	10/02/2022 10/02/2022 10/02/2022 10/02/2022 10/02/2022 10/02/2022	10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous           10/02/2022         Spontaneous	10/02/2022Spontaneous ProfessionalNon Healthcare Professional10/02/2022Spontaneous ProfessionalNon Healthcare Professional10/02/2022Spontaneous ProfessionalNon Healthcare Professional10/02/2022Spontaneous ProfessionalNon Healthcare Professional10/02/2022Spontaneous Professional10/02/2022Spontaneous Professional10/02/2022Spontaneous Professional10/02/2022Spontaneous Professional	10/02/2022       Spontaneous Pleatthcare Professional Area       European Economic Professional Area         10/02/2022       Spontaneous Professional Professional Professional Professional Area       European Economic Professional Area         10/02/2022       Spontaneous Professional Profes	10/02/2022 Spontaneous Non Healthcare Professional Reconomic Profess	10/02/2022 Spontaneous Professional Perofessional Perofess	10/02/2022   Spontaneous   Non recessional   Surposan Recommer   Not waliable   Non the Professional Recommer   Not w	10/02/2022   Spontaneous   Montesthicane   European   Not available   Specified   Month   Mo	10/02/2022   Spontaneous   Non Healthcare   European   Not Economic   Professional   Professio	Part   Part	2002/2012   Springeroom   Sp	Registration   Regi

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										Hospitalisation), Emotional distress (n/a - Fatal - Results in Death, Caused/Prolonged	applicable - [1d - n/a - Transmammary])		
										Hospitalisation),  Exposure via breast milk (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
										Failure to thrive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
										Hepatic enzyme increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
										Insomnia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
										Rash (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
										Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)			
EU-EC- 10011548862	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011549998	09/02/2022	Spontaneous		European Economic Area	Not available	2	Not Specified	Male	No	Blister (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - ),			
EU-EC-	09/02/2022	Spontaneous	Non	European	Not	2	Infant	Ma <b>l</b> e	Yes	Listless (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011551210				Economic	available	Months - 2 Years				milk (n/a - Unknown - ), Faeces discoloured (2wk - Recovered/Resolved -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	,	
EU-EC- 10011551861	09/02/2022	Spontaneous		Non European Economic Area	Not available	0-1 Month	Not Specified	Female	No	) Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSR
										Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Exposure via breast milk (n/a - Unknown - ),			
										Infant irritability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Livedo reticularis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rash (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			

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										Condition),  Rash macular (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Viral infection (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vomiting projectile (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011554231	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Malaise (2d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mg - n/a])	Not reported	ICSR
EU-EC- 10011556868	09/02/2022	Spontaneous		European Economic Area	Not available	Months - 2	Infant	Female	No	Disturbance in attention (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICSR
						Years				Fatigue (n/a - Unknown - ), Tinnitus (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])		
EU-EC- 10011556916	09/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Hypertension (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Swollen tongue (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Urticaria (n/a -			
										Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10011557702	09/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Infant	Male	No	Abnormal faeces (2d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Faeces discoloured (2d - Recovering/Resolving - ), Pyrexia (2d - Recovering/Resolving			
EU-EC- 10011557752	09/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2	Child	Female	No	Fatigue (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011528160	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Years 0-1 Month	Adult	Male	No	Fatigue (1d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (4d - Unknown - ),			
										Rash pruritic (1d - Recovering/Resolving -), Tremor (1d -			
EU-EC-	08/02/2022	Spontaneous		European	Not		Adult	Female	No	Recovering/Resolving - ) Dizziness (0d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011528251			Healthcare Professional	Economic Area	available	Month				Recovering/Resolving -), Syncope (0d - Recovering/Resolving	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011528284	08/02/2022	Spontaneous	Healthcare	European Economic	Not available	0-1 Month	Adult	Female	No	- ) Asthenia (1d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional	Area						Resolved - ),  Chills (1d - Not Recovered/Not Resolved - ),	- n/a - n/a])		
										Headache (1d - Not Recovered/Not Resolved - ),			
										Nausea (1d - Not Recovered/Not Resolved - ),			
										Pain in extremity (1d -			

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EU-EC-	08/02/2022	Spontaneous		European	Not	2	Elderly	Male	No	Resolved - ) Chills (2d -		Not reported	ICS
10011528291			Healthcare Professional	Economic Area	available	Months - 2 Years				Recovered/Resolved - ), Diarrhoea (2d - Recovered/Resolved - )	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Fatigue (2d - Recovered/Resolved -			
EU-EC- 10011528313	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Diarrhoea (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Fatigue (3d - Recovered/Resolved - ),			
										Headache (1d - Recovered/Resolved - )			
EU-EC- 10011528452	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Injection site pain (5d - Recovered/Resolved - ), Swelling of eyelid (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011528491	08/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	2 Months	Elderly	Male	No	- ) Herpes zoster (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICS
EU-EC-	08/02/2022	Spontaneous	Professional		Not	- 2 Years	Elderly	Female	No	Resolved - )  Dizziness (1d -	- n/a - n/a])  COMIRNATY [TOZINAMERAN]	Not reported	ICS
10011528845		·	Healthcare Professional	Economic Area	available	Months - 2 Years				Recovered/Resolved - )	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011528926		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Eye infection (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011529079	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Limb discomfort (1d - Recovered/Resolved - ), Pain in extremity (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011529089	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	0-1 Month	Adult	Male	No	Recovered/Resolved - ) Ear pain (6d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
			Fioressional	Alea						Malaise (6d - Not Recovered/Not Resolved - )	- 11/4 - 11/4])		
EU-EC- 10011535483	08/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011536674	08/02/2022	Spontaneous	Non Healthcare Professional		Not available	2 Months - 2 Years	Infant	Male	No	Abdominal pain (n/a - Unknown - ), Crying (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),			
										Gastrointestinal motility disorder (n/a - Unknown - ),			
										Headache (n/a - Unknown - ),			
										Pallor (n/a - Unknown - ), Pyrexia (n/a -			
										Unknown - ), Sleep disorder (n/a -			
EU-EC- 10011537568	08/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	2 Months	Adult	Male	No	Unknown - ) Pruritus (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF
			Professional			- 2 Years				Resolved - ), Urticaria (n/a - Not Recovered/Not	- n/a - Intramuscular])		
EU-EC- 10011539085	08/02/2022	Spontaneous	Healthcare Professional		Not available	2 Months	Adult	Female	No	Resolved - ) Pericarditis (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-	ICS
FIL FO	07/02/2022	Constant	New	Area	Note	- 2 Years	Nuch	24-1-	N.	Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - Intramuscular])	024414)] (C - n/a - n/a - [28d - n/a - n/a])	1001
EU-EC- 10011514670	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	пос герогсеа	ICSI
EU-EC- 10011515982		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a3mL - Intramuscular])	Not reported	ICS
						icais				Milk allergy (n/a - Unknown - ),	and an ascalar j)		
										Urticaria (2wk - Recovered/Resolved - )			
EU-EC- 10011516105		Spontaneous	Non Healthcare		Not available	2 Months	Not Specified	Male	No	Injection site swelling (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a		ICSF

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			Professional	Area		- 2 Years				Recovered/Resolved -	- n/a - n/a])		
EU-EC- 10011516166	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011526970	07/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza (2d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Swelling face (2d - Recovering/Resolving - )			
EU-EC- 10011526978	07/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Eye pain (2d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (2d - Recovering/Resolving - ),			
										Swelling face (2d - Recovering/Resolving - )			
EU-EC- 10011527037	07/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (2d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (2d - Recovering/Resolving - ),			
										Menstrual disorder (n/a - Recovering/Resolving -),			
										Nausea (2d - Recovering/Resolving - ),			
										Vertigo (2d - Recovering/Resolving - )			
EU-EC- 10011527100	07/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Arrhythmia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (n/a - Recovering/Resolving - ),			
										Dizziness (n/a - Recovering/Resolving - ),			
										Dyspnoea (n/a - Recovering/Resolving - ),			
										Tinnitus (n/a - Recovering/Resolving - )			
EU-EC- 10011527125	07/02/2022	Spontaneous	Non Healthcare Professional		Not available		Adult	Female	No	Appetite disorder (2d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
										Chills (2d - Recovering/Resolving  - ),			
										Dizziness (2d - Recovering/Resolving - ),			
										Feeling hot (n/a - Recovering/Resolving - ),			
										Malaise (2d - Recovering/Resolving			
										Tachycardia (2d - Recovering/Resolving -)			
EU-EC- 10011527143	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2	Elderly	Female	No	Dizziness (1d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
						Years				Hypoaesthesia (1d - Recovering/Resolving - ),			
										Myalgia (2d - Recovering/Resolving - ),			
										Paraesthesia (1d - Recovering/Resolving -),			
										Tachycardia (1d - Recovered/Resolved -			
EU-EC- 10011527328	07/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Chills (0d - Recovered/Resolved - ),	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
						icais				Dizziness (0d - Recovered/Resolved - ),			
										Fatigue (0d - Recovered/Resolved -			

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										), Gait disturbance (0d - Recovered/Resolved - ),			
										Headache (0d - Recovered/Resolved -			
EU-EC- 10011527416	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Male	No	Fatigue (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Local reaction (1d - Recovered/Resolved - ),			
										Vaccination site pain (1d - Recovered/Resolved -			
EU-EC- 10011527471	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Body temperature increased (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]),	Not reported	ICSF
										Bone pain (1d - Recovering/Resolving -),	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a -		
										Lymphadenopathy (1d	n/a - n/a])		
										Recovering/Resolving - ),			
										Peripheral swelling (1d -			
										Recovering/Resolving - ),			
										Tachycardia (1d - Recovering/Resolving -),			
										Vomiting (1d - Recovering/Resolving - )			
EU-EC- 10011527561	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	0-1 Month	Adult	Female	No	- Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF
EU-EC- 10011527755	07/02/2022	Spontaneous	Non	European Economic	Not available	0-1 Month	Adult	Female	No	Headache (0d - Recovering/Resolving - ),	- n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Musculoskeletal stiffness (0d - Recovering/Resolving -),			
										Myalgia (0d - Recovering/Resolving -),			
										Neck pain (0d - Recovering/Resolving - ),			
										Vaccination site pain (0d - Recovering/Resolving -)			
EU-EC- 10011527959	07/02/2022	Spontaneous	Healthcare	European Economic	Not available	0-1 Month	Adult	Female	No	Fatigue (0d - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF
			Professional	Area						Lymphadenopathy (42d - Not Recovered/Not Resolved - )	- n/a - n/a])		
EU-EC- 10011528072	07/02/2022	Spontaneous		European Economic	Not available	0-1 Month	Adult	Female	No	Dizziness (4d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
			riolessional	Area						Injection site pain (4d	- 1/4 - 1/4])		
										Recovering/Resolving			
EU-EC- 10011507336	06/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Adult	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Injection site pain (1d - Recovered/Resolved - ),			
										Listless (1d - Recovered/Resolved -			
EU-EC- 10011512621	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site erythema (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011502198	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Hypotonia (n/a - Not Recovered/Not Resolved - ),			
										Limb discomfort (n/a - Not Recovered/Not Resolved - ),			

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										Muscle twitching (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011502286	05/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Not Specified	Female	No	Exposure via breast milk (1d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Faeces discoloured (1d - Recovering/Resolving -)			
EU-EC- 10011502311	05/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Ma <b>j</b> e	No	Herpes virus infection (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011502818	05/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - ), Weight decreased	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011503219		Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Diarrhoea (0d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011506105		Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011506191	05/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Chills (2d - Unknown - ), Headache (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]),	Not reported	ICSR
										Unknown - ), Limb discomfort (2d - Unknown - ),	VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - Immunisation - n/a - [n/a -		
										Myalgia (2d - Unknown - ),	n/a - n/a])		
										Rash (n/a - Unknown - ), Urticaria (n/a -			
EU-EC- 10011506193	05/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Unknown - ) Fatigue (3d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (3d - Recovering/Resolving - ),	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
										Limb discomfort (3d - Recovering/Resolving - )			
EU-EC- 10011506335	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain (1d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Back pain (1d - Recovering/Resolving -),			
										Injection site pain (1d - Recovering/Resolving - ),			
										Nausea (1d - Recovering/Resolving - )			
EU-EC- 10011506462	05/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Rash (30d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Urticaria (30d - Not Recovered/Not Resolved - )			
EU-EC- 10011496286	04/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496311	04/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496334	04/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496336	04/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496345	04/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496367	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	04/02/2022	Spontaneous	Non	European	Not	2	Not	Female	No	Injection site pain (2d	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10011496370			Healthcare Professional		available	Months - 2 Years	Specified			- Recovered/Resolved - )	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011496381	04/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011496513	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Injection site erythema (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011497818	04/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Injection site swelling (2d - Recovered/Resolved - )			
EU-EC- 10011486056	03/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Infant	Male	No	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Staphylococcal scalded skin syndrome (8d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011472480	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Arrhythmia (7d - Not Recovered/Not Resolved - ), Bradycardia (7d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU EC	02/02/2022	Chantanaous	Non	Europoan	Not	2	Adult	Eomala	No	Recovered/Not Resolved - )	COMIDNATY [TOZINAMEDAN]	Not reported	TCC
EU-EC- 10011472486	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	Months - 2 Years	Adult	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										- Recovered/Resolved - )			
EU-EC- 10011472510	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Feeling hot (37d - Recovering/Resolving -), Injection site pain (1d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										- Unknown - ), Sleep disorder (37d - Recovering/Resolving			
EU-EC- 10011473781	02/02/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Abdominal pain lower (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
										Arthropathy (n/a - Recovering/Resolving - ),			
										Cystitis (n/a - Recovering/Resolving -),			
										Streptococcal urinary tract infection (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Yersinia infection (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10011475739	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Male	No	Important Condition)  Dry skin (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	Not reported	ICSR
										Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved - ),	Transplacement		
										Skin exfoliation (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10011475946	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Rash (6d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011450229	01/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	Crying (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011462468	01/02/2022	Spontaneous		Non European Economic Area	Not available	2	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Cough (n/a - Recovering/Resolving - ),			
										Nasopharyngitis (n/a - Recovering/Resolving - ),			
										Off label use (n/a - Unknown - ), Product administered			
										to patient of			

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										inappropriate age (n/a - Unknown - ),			
										Pyrexia (34h - Recovered/Resolved - ),			
										Vaccination site swelling (n/a - Recovering/Resolving			
EU-EC- 10011462475	01/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	No	Diarrhoea (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSF
EU-EC- 10011462534	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	2	Not Specified	Female	No	No adverse event (21d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSF
EU-EC- 10011462556	01/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Ma <b>l</b> e	No	No adverse event (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSF
EU-EC- 10011462560	01/02/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Diarrhoea (35d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSF
EU-EC- 10011437329	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	2	Not Specified	Ma <b>l</b> e	No	Injection site erythema (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSF
EU-EC- 10011438287	31/01/2022	Spontaneous		European Economic Area	Not available	2	Not Specified	Not Specified	No	Depressed mood (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transmammary])	Not reported	ICSF
						,				Exposure via breast milk (n/a - Recovered/Resolved - ),	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
										Insomnia (n/a - Recovered/Resolved - ),			
										Irritability (n/a - Recovered/Resolved - ),			
										Limb mass (n/a - Recovered/Resolved - ),			
										Middle insomnia (n/a - Recovered/Resolved - ),			
										Oedema peripheral (n/a - Recovered/Resolved - ),			
										Peripheral swelling (n/a - Recovered/Resolved -			
										Pyrexia (n/a - Recovered/Resolved -			
										Skin discolouration (n/a - Recovered/Resolved -			
EU-EC- 10011441723	31/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Influenza (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011441756		Spontaneous	Non	European Economic	Not available	2 Months - 2 Years	Child	Ma <b>l</b> e	No	Rash (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011431669	30/01/2022	Spontaneous		European Economic Area	Not available	2	Not Specified	Male	No	No adverse event (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011431680	30/01/2022	Spontaneous		European Economic Area	Not available	2	Not Specified	Male	No	No adverse event (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011432311	30/01/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Ma <b>l</b> e	No	No adverse event (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011433127	30/01/2022	Spontaneous		European Economic Area	Not available	2	Not Specified	Male	No	Pyrexia (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011434980	30/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Dizziness (1d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-	30/01/2022	Spontance	Non	Furonoss	Not	2	Not	Male	No	Somnolence (1d - Not Recovered/Not Resolved - )	COMIDNATA LACATIVAMENANA	Not reported	ICCD
10011435638		Spontaneous	Healthcare Professional		Not available	Months - 2 Years	Not Specified	Male	No	No adverse event (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011435718		Spontaneous	Healthcare Professional		Not available	2 Months - 2 Years		Male	No	No adverse event (n/a - Unknown - )	(S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011421879	28/01/2022	Spontaneous		European Economic	Not available	2 Months	Infant	Not Specified	Yes	Exposure via breast milk (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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			Professional	Area		- 2 Years				Recovered/Resolved - ),  Pyrexia (2d -	Not applicable - [1d3mL - Transmammary])		
EU-EC- 10011399167	27/01/2022	Spontaneous		European Economic	Not available	0-1 Month	Not Specified	Male	Yes	Recovered/Resolved - ) Faeces discoloured (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICS
EU-EC- 10011405958	27/01/2022	Spontaneous	Non	Non European	Not available	0-1 Month	Not Specified	Male	Yes	Exposure via breast milk (n/a - Unknown - ),	Transmammary])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
				Area						Pyrexia (72h - Recovered/Resolved - ),	Transmammary])		
										Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Viral infection (n/a - Unknown - )			
EU-EC- 10011410054	27/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Limb discomfort (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Nasopharyngitis (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10011389318	26/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
										Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition),	Transmammary - More in ICSR])		
										Malaise (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011389738	26/01/2022	Spontaneous	Healthcare	European Economic	Not available	0-1 Month	Adult	Female	No	Menstrual disorder (10d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSI
EU-EC- 10011389743	26/01/2022	Spontaneous	Non	Area European Economic	Not available	0-1 Month	Adult	Male	No	Cardiovascular disorder (0d -	- n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICS
100110037 10			Professional		aranasis					Recovered/Resolved - ),  Pyrexia (0d -	- n/a - n/a])		
EU EC	26 (01 /2022	Constant	Nan	F	Not	0.1	0 -1 -12	EI.	N-	Recovered/Resolved - )	CONTRIATO ETOZINAMEDANI	Net were the d	TOCI
EU-EC- 10011389903	26/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Diarrhoea (3d - Recovered/Resolved - ), Pain in extremity (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Resolved -			
EU-EC- 10011396915	26/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Paraesthesia (14d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011396954	26/01/2022	Spontaneous	Non	European Economic	Not available	0-1 Month	Adult	Female	No	Back pain (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Chills (2d - Recovered/Resolved - ),			
										Cough (2d - Recovered/Resolved - ),			
										Injection site pain (3d - Recovered/Resolved - ),			
										Myalgia (2d - Recovered/Resolved - ),			
										Oropharyngeal pain (2d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved -			
EU-EC- 10011397089	26/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Male	No	Arthralgia (4d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Breast pain (4d - Recovered/Resolved - ),			
										Dyspnoea (4d -			

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										Oropharyngeal pain (4d - Recovered/Resolved - ),			
										Pain in jaw (4d - Recovered/Resolved -			
EU-EC- 10011397103	26/01/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
						leais				Injection site pain (1d - Recovered/Resolved			
EU-EC- 10011397562	26/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	- )   Injection site pain (2d  - Recovered/Resolved  - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011384729	25/01/2022	Spontaneous		European Economic Area	Not available	2	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
						leais				Poor feeding infant (4d - Recovered/Resolved -	maismainnaryj)		
EU-EC- 10011361411	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Agitation (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Exposure via breast milk (n/a - Recovered/Resolved -			
										Infant irritability (n/a - Recovered/Resolved -			
EU-EC- 10011366137	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Ma <b>l</b> e	Yes	Crying (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Transmammary])	Not reported	ICSR
										Exposure via breast milk (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10011367767	24/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	Yes	Diarrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Exposure via breast milk (n/a - Unknown - )			
EU-EC- 10011368227	24/01/2022	Spontaneous	Non Healthcare Professional			0-1 Month	Neonate (Preterm and Term newborns)	Female	Yes	Foetal malnutrition (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [21d - 2{DF} - Transplacental])	Not reported	ICSR
EU-EC- 10011368751	24/01/2022	Spontaneous		European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Crying (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
						rears				Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),			
										Infant sedation (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10011368760	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	0-1 Month	Not Specified	Not Specified	Yes	Important Condition)  Exposure via breast milk (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICSR
										Important Condition),  Haematochezia (n/a - Recovered/Resolved -	Transmanniary))		
										Other Medically Important Condition)			
EU-EC- 10011370111	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	<u>ICSR</u>
										Disease recurrence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Exposure via breast milk (n/a - Unknown - Caused/Prolonged			
										Hospitalisation),  Malaise (n/a - Recovered/Resolved - Caused/Prolonged			
										Hospitalisation), Pyrexia (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			

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EU-EC- 10011370278	24/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available		Not Specified	Female	Yes	Hospitalisation) C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Exposure via breast milk (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Leukocytosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
:U-EC- .0011370684	24/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Angioedema (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Urticaria (1d - Recovered/Resolved - )			
EU-EC- 10011371027	24/01/2022	Spontaneous	Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Exposure via breast milk (n/a - Unknown - Other Medically Important Condition),			
										Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Irritability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- L0011341906	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Male	Yes	Epistaxis (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Transmammary])	[LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a -	ICS
												[n/a - n/a - n/a]), [SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE] (C -	
EU-EC- 10011345616	21/01/2022	Spontaneous		European Economic	Not available	Months	Infant	Female	Yes	Exposure via breast milk (n/a - Unknown -	(S - COVID-19 immunisation -	n/a - n/a - [n/a - n/a - n/a])   [DESOGESTREL] (C - n/a - n/a -   [n/a - n/a - n/a])	ICS
			Professional	Area		- 2 Years				), Fatigue (n/a - Not Recovered/Not Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])		
										Poor feeding infant (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- L0011351475	21/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Not Specified	Not Specified	Yes	Exposure via breast milk (n/a - Unknown - ), Faeces discoloured	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transmammary])	Not reported	ICS
										(3wk - Recovered/Resolved - ),			
										Infant irritability (n/a - Recovered/Resolved - ),			

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										Tearfulness (n/a - Recovered/Resolved -			
U-EC- 0011353915	21/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Elderly	Female	No	Herpes zoster (n/a - Recovering/Resolving - ), Lymphadenopathy (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011324519	20/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (21d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011325412	20/01/2022	Spontaneous		European Economic	Not available	2 Months - 2 Years	Child	Male	No	Chills (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011325448	20/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	2 Months - 2 Years	Child	Male	No	Fatigue (n/a - Recovered/Resolved - )	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011325602	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	2 Months - 2 Years	Child	Female	No	Application site pain (n/a - Recovered/Resolved - ), Off label use (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011326989	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (2d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Injection site pain (2d - Recovered/Resolved - ), Myalgia (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011328003	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	Fatigue (0d - Not Recovered/Not Resolved - ), Injection site pain (0d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011328034	20/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	0-1 Month	Adult	Female	No	resolved - ) Dizziness (0d - Recovered/Resolved - ), Fatigue (4d - Recovering/Resolving - ), Headache (2d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011328095	20/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (n/a - Not Recovered/Not Resolved - ), Nausea (0d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSF
EU-EC- 10011328576	20/01/2022	Spontaneous		European Economic Area	Not available	0-1 Month	Adult	Female	No	Headache (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF



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