Line Listing Report Time run: 30/11/2022 03:16:53

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	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])	
EU-EC- 10012760828	17/06/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthma (n/a - Not Recovered/Not Resolved -), Heart disease congenital (n/a - Not Recovered/Not Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Important Condition), Obesity (n/a - Not Recovered/Not Resolved -			
EU-EC- 10012766299	17/06/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Acquired phimosis (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
				Area						Keratitis (n/a - Unknown -), Phimosis (n/a - Unknown -	immunisation - Not applicable - [1d - n/a - n/a])		
), Stevens-Johnson syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Toxic epidermal necrolysis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vision blurred (n/a - Unknown -),			
										Visual acuity reduced (n/a - Unknown -)			L
EU-EC- 10012766311	17/06/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Angioedema (10d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICS</u>
										Dizziness (n/a - Recovered/Resolved -),	.2mL - Intramuscular])		
										Erythema (n/a - Not Recovered/Not Resolved -),			
										Fall (n/a - Recovered/Resolved -),			
										Idiopathic urticaria (n/a - Unknown -),			
										Nausea (n/a - Recovered/Resolved -),			
										Pallor (n/a - Recovered/Resolved -),			
										Pruritus (n/a - Not Recovered/Not Resolved -),			
										Urticaria (155h - Recovered/Resolved -)			
EU-EC- 10012767161	17/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Headache (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - n/a - n/a])		
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Somnolence (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012768948	17/06/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
EU-EC-	17/06/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Male	No	Pyrexia (1d -	Intramuscular]) COMIRNATY	Not reported	ICS
10012771471	,			European Economic Area	available	Years	Specified			Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		

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	EU-EC- 10012773015	17/06/2022	Spontaneous			Not available	3-11 Years	Child	Female	No	Abdominal pain (13d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[METHOTREXATE] (C - Juvenile idiopathic arthritis - n/a - [35d - 12.5mg - n/a])	ICSR
											Colitis ischaemic (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
											Diarrhoea (11d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Disseminated intravascular coagulation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Dysphonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Haematochezia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Headache (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Mental status changes (0d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Multisystem inflammatory syndrome in children (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Oropharyngeal pain (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Pyrexia (8d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Renal failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Shock (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Vomiting (4d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
	EU-EC- 10012740433	16/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (15min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
	EU FO	16/06/2022	Charter	Hools-	Mov	Not	2.11	Not	Mal-	Ne	Tetany (15min - Recovered/Resolved - Other Medically Important Condition)	- Intramuscular])	Net reported	TCCC
	EU-EC- 10012740574	16/06/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
	EU-EC- 10012740707	16/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Gastroenteritis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
			1	1				1			1	1		

0.11.2022 0		I	I	ı	ı		ı	ı (dir L		Julius and Other Medically	landratic feet of	ı	ı
										Unknown - Other Medically Important Condition)	applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012741073	16/06/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Poor quality product administered (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Product administration error (n/a - Unknown -)	immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012741727	16/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bradycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	- n/a])		
										Discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012745648	16/06/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Ketosis (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Meningitis (n/a - Unknown - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Meningitis aseptic (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10012745758	16/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	OLOPATADINE [OLOPATADINE] (C - Rhinitis allergic - n/a - [n/a - n/a - Oral]),	ICSR
										Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - Intramuscular])	[DERMATOPHAGOIDES FARINAE EXTRACT, DERMATOPHAGOIDES PTERONYSSINUS EXTRACT] (C - Immunisation - n/a - [n/a - n/a - Sublingual]),	
												[MONTELUKAST, MONTELUKAST SODIUM] (C - Rhinitis allergic - n/a - [n/a - n/a - Oral])	
EU-EC- 10012745773	16/06/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Costochondritis (n/a - Recovering/Resolving -),	immunisation - Not applicable - [1d - n/a		
										Decreased appetite (n/a - Recovering/Resolving -),	- n/a])		
										Dyspnoea (n/a - Recovering/Resolving -),			
										Gastrooesophageal reflux disease (n/a -			
										Recovering/Resolving -), Headache (n/a - Recovering/Resolving -),			
										Interchange of vaccine products (n/a -			
										Recovering/Resolving -), Lethargy (n/a -			
										Recovering/Resolving -), Musculoskeletal pain (n/a -			
										Recovering/Resolving -),			
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Off label use (n/a - Recovering/Resolving -)			
EU-EC- 10012752405	16/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Hot flush (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Nausea (n/a - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012754153	16/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hepatic enzyme increased (24d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Hepatic function abnormal	applicable - [1d - n/a - n/a])		

30.11.2022 C	3.24							Run L	ine Lis	sting Report			
										(23d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Neutrophil count decreased (23d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (25530min - Recovered/Resolved -),			
										White blood cell count decreased (23d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012754317	16/06/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10012754350	16/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>ICSR</u>
										Myocarditis (n/a - Unknown - Other Medically Important Condition),	.5mL - n/a])		
										Overdose (n/a - Recovered/Resolved -),			
										Pain (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Syncope (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										White blood cell count increased (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012723922	15/06/2022	Spontaneous	Healthcare	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Cough (n/a - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Feeling cold (n/a - Unknown - Other Medically Important Condition),			
										Flushing (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Malaise (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nasopharyngitis (2wk - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012724770	15/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Pyrexia (n/a - Unknown -)	immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10012724939	15/06/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 10ug - n/a])	Not reported	ICSR
EU-EC- 10012725853	15/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Oral herpes (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Urticaria (n/a - Unknown - Other Medically Important Condition)			
EU-EC-	15/06/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Dyspnoea (n/a - Not	COMIRNATY	Not reported	<u>ICSR</u>

0.11.2022 0	3.24							Run L	ine Li	sting Report			
10012727078			Healthcare Professional		available	Years				Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10012727084	15/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Recovered/Not Resolved -) Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Weight bearing difficulty (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC-	15/06/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Hospitalisation) Fatigue (1d -	COMIRNATY	Not reported	ICSR
10012727096	13/00/2022	Sportaneous	Healthcare Professional	Economic	available	Years	Ciliu	Temale	NO	Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSK</u>
										Vomiting (1d - Recovered/Resolved -)			
EU-EC- 10012727585	15/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Headache (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Product preparation issue (n/a - Unknown -), Somnolence (2d -	immunisation - Not applicable - [n/a - .2mL - Intramuscular])		
EU-EC-	15/06/2022	Chantanagua	Non	Non	Not	3-11	Not	Fomale	No	Recovered/Resolved -)		Not reported	ICCD
10012729569	15/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	- n/a])		
EU-EC- 10012712845	14/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Appendicitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012713227	14/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012713336	14/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012713355	14/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10012714581	14/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Nausea (n/a - Unknown -), Off label use (n/a -	immunisation - Not applicable - [n/a - n/a - n/a])		
										Unknown -), Product use issue (n/a -			
EU-EC-	14/06/2022	Spontaneous		Non	Not	3-11	Not	Male	No	Unknown -) COVID-19 (n/a -	COMIRNATY CTOZINAMERANI (C	[DESMOPRESSIN,	ICSR
10012715072			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	DESMOPRESSIN ACETATE] (C - Enuresis - n/a - [n/a - n/a - Oral])	
										Unknown - Other Medically Important Condition)			
EU-EC- 10012716328	14/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Ageusia (2d - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Fatigue (2d - Recovered/Resolved -),	n/a - n/a])		
										Headache (2d - Recovered/Resolved -),			

J.11.2022 U	3.24							Run L	ine Lis	sung Report			
										Hyperhidrosis (2d - Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -),			
										Myalgia (2d - Recovered/Resolved -),			
										Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 10012716963	14/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC- 10012718344	14/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Condition) Headache (2250min - Recovered/Resolved -), Overdose (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Product preparation error (n/a - Unknown -),	applicable - [n/a - n/a - Intramuscular])		
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012721676	14/06/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			Troressional	/ ii cu						Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (3d -	immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10012701479	13/06/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Recovered/Resolved -) Pyrexia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S -	GLYCOPYRRONIUM BROMIDE	ICSR
			Professional	Area						Salivary hypersecretion (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[GLYCOPYRRONIUM BROMIDE] (C - n/a - Unknown - [n/a - n/a - n/a]),	
										Tachycardia (n/a - Recovering/Resolving -)		[AZITHROMYCIN] (C - n/a - Unknown - [n/a - n/a - n/a]),	
												[DIMETINDENE MALEATE] (C - n/a - Unknown - [n/a - n/a - n/a])	
EU-EC- 10012702940	13/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Encephalopathy (n/a - Unknown - Other Medically Important Condition), Influenza A virus test	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
EU-EC- 10012703937	13/06/2022	Spontaneous	Non Healthcare	European	Not available	3-11	Child	Male	No	positive (n/a - Unknown -) Angina pectoris (n/a -	- n/a]) COMIRNATY	Not reported	ICSR
10012/0393/				Economic Area	avallable	Years				Recovered/Resolved -), Cardiac discomfort (n/a - Recovered/Resolved -)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10012704928	13/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012705819	13/06/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vertigo (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012706309	13/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	- Intramuscular])		
		Spontaneous	1	European	Not	3-11	Neonate	Female	No	· · · · · · · · · · · · · · · · · · ·	COMIRNATY	Not reported	ICSR G/F

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10012711535			Healthcare Professional	Economic Area	available	Years	(Preterm and Term newborns)			Not Recovered/Not Resolved -), Headache (244d - Not Recovered/Not Resolved -), Influenza like illness (244d - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Pain in extremity (244d - Not Recovered/Not			
EU-EC- 10012697068	11/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Resolved -) Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012697181	11/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012697256	11/06/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Gait disturbance (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash pruritic (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Speech disorder (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012685447	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Capillary fragility (n/a - Recovered/Resolved -), Conjunctival haemorrhage (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012688263	10/06/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Body temperature increased (n/a - Unknown -), Decreased appetite (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012689018	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[DESLORATADINE] (C - Hypersensitivity - n/a -)	ICSR
EU-EC- 10012689528	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Epilepsy (3min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[VALPROIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10012690901	10/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypersensitivity (463min - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012692002	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012692914	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved -), Rash pruritic (n/a - Recovered/Resolved -), Skin lesion (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

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										Recovered/Resolved -),			
										Vaccination site pain (n/a - Unknown -)			
EU-EC- 10012694226	10/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10012694943	10/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSF</u>
EU-EC-	10/06/2022	Spontaneous		European	Not	3-11	Child	Male	No	Gianotti-Crosti syndrome	COMIRNATY	Not reported	ICSR
10012695684			Professional	Economic Area	available	Years				(n/a - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -		
										Prurigo (18d - Recovered/Resolved - Other Medically Important Condition)	.2mL - Intramuscular])		
EU-EC- 10012696053	10/06/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Fatal - Results in Death,	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
10012030033			Torcasional	Economic Area	avanable	rears	эрестеч			Caused/Prolonged Hospitalisation),	COVID-19 immunisation - Not applicable - [1d - n/a		
										Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	- Intramuscular])		
EU-EC- 10012674938	09/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not	Not reported	ICSR
										Pallor (0d - Recovered/Resolved - Other Medically Important	applicable - [n/a - 10ug - Intramuscular])		
EU-EC- 10012676934	09/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Condition) Malaise (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving -), Syncope (n/a -	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
FILES	00/06/2022	C	1114	F	NI-4	2.11	Not	N4-1-	N1 -	Recovering/Resolving -)	COMPRAINT	Networked	TCCD
EU-EC- 10012677568	09/06/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Overdose (n/a - Unknown -), Product preparation error (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Vaccination site pain (n/a - Unknown -)	applicable - [n/a - 10ug - n/a])		
EU-EC- 10012680683	09/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10012680687	09/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Diarrhoea (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - Intramuscular])		
										Pyrexia (10d - Recovered/Resolved - Caused/Prolonged			
EU-EC-	09/06/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Male	No	Hospitalisation) Erythema multiforme (n/a	COMIRNATY	Not reported	ICSR
10012680883			Professional		available	Years	Specified			- Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		
EU-EC-	09/06/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Female	No	Decreased appetite (n/a -	- n/a]) COMIRNATY	Not reported	ICSR
10012681434	. ,		Professional	European Economic Area	available	Years	Specified			Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		
										Dysstasia (n/a - Recovered/Resolved - Other Medically Important Condition),	- Intramuscular])		
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Gait disturbance (n/a - Recovered/Resolved - Other Medically Important Condition),			

										sung Report			
										Hypoglycaemia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
U-EC- L0012681498	09/06/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
				Economic Area						Asthenia (n/a - Unknown -),	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Blood creatine phosphokinase increased	in a meramascalar jy		
										(n/a - Recovering/Resolving -			
										Caused/Prolonged Hospitalisation),			
										Cardiomegaly (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Cardiomyopathy (n/a - Recovering/Resolving -			
										Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Chest pain (n/a - Unknown -),			
										Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Decreased appetite (n/a - Recovering/Resolving -),			
										Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Condition),			
										Electrocardiogram abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Fibrin D dimer increased (n/a - Unknown -),			
										Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovered/Resolved - Life			
										Threatening, Caused/Prolonged			
										Hospitalisation, Other Medically Important Condition),			
										Nutritional condition abnormal (n/a - Unknown			
										Oropharyngeal pain (n/a - Unknown -),			
										Pericarditis (n/a - Recovered/Resolved - Life			
										Threatening, Caused/Prolonged			
										Hospitalisation, Other Medically Important Condition),			
										Pharyngeal erythema (n/a - Unknown -),			
										Pharyngeal swelling (n/a - Unknown -),			
										Pyrexia (206h - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Troponin I increased (n/a - Unknown -),			
							1			"""			

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										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Viral pharyngitis (n/a - Unknown -),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012682094	09/06/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Decreased appetite (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
				Alea						Pyrexia (2d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012683005	09/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - Intramuscular])		
										Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate decreased (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hypotension (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012683459	09/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	<u>IC</u>
										Nephrotic syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	- n/a])		
										Renal disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012684130	09/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Haematoma (n/a - Recovered/Resolved -), Inflammation (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	IC
EU-EC- 10012663483	08/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	IC
EU-EC- L0012664398	08/06/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>IC</u>
										Blood pressure decreased (40min - Recovered/Resolved -),	.2mL - Intramuscular])		
										Cough (40min - Recovered/Resolved -),			
										Dysphonia (40min - Recovered/Resolved -),			
										Oropharyngeal discomfort (n/a - Recovered/Resolved -),			
										Pallor (40min - Recovered/Resolved -),			
										Respiratory symptom (n/a - Recovered/Resolved -)			
EU-EC- 10012665433	08/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Abdominal pain upper (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Asthenia (n/a - Unknown -),			
										Diarrhoea (n/a - Unknown			

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Delication Del														
United December											Pyrexia (n/a - Unknown -),			
											Vomiting (n/a - Unknown -			
UNITED CONTRIBUTION SPECIAL PROPERTY OF THE PR	EU-EC- 10012666232	08/06/2022	Spontaneous		Economic				Male	No		[TOZINAMERAN] (S -	Not reported	ICSR
1945					Alea						Chills (n/a - Unknown -),			
19-60														
Colorado														
Hardinaria Personal Area Perso	EU-EC-	08/06/2022	Spontaneous	Non	European	Not	3-11	Not	Male	No		COMIRNATY	Not reported	ICSR
March Marc	10012666637		·			available	Years	Specified			Caused/Prolonged	COVID-19 immunisation - Not	·	
Section Content (Content) Content (Content (Content) Content (Content (Content) Content (Content (Content (Content) Content (Content (Unknown - Other Medically			
13-5C 13-5											- Other Medically			
1.14 Dec Continuous Con														
Healthcare Secondary Sec											Unknown - Other Medically			
ULFC- 0012671209 Sportaneous Professional Expression (No. 1) Professional Area No. 1) No. 1) No. 1) No. 1) No. 2) No. 2) No. 2) No. 2) No. 2) No. 3) No. 3) No. 3) No. 4) No. 2) No. 4) No. 4) No. 4) No. 4) No. 4) No. 4) No. 6) No. 6) No. 6) No. 6) No. 6) No. 7)	EU-EC- 10012669903	08/06/2022	Spontaneous	Healthcare	Economic				Male	No	Recovered/Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
BUREC O7/06/2022 Sportaneous Non Healthcare Aven Av	EU-EC- 10012671209	08/06/2022	Spontaneous		European Economic				Female	No	Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
Professional Area Professional Area Professional Female U-EC- 0012654374 Professional Female Professional Fem	EU-EC- 10012671554	08/06/2022	Spontaneous					Child	Female	No		COMIRNATY	Not reported	ICSR
Discrimination Disc				Professional	Area						Product prescribing error (3d - Recovered/Resolved	COVID-19 immunisation - n/a - [n/a - 1{DF} -		
Area Area Area Area Chest pain (n/a - Unknown -), Head injury (n/a - Unknown -), Sencope (n/a - Unknown -), Read injury (n/a - Unknown -), Sencope (n/a - Unknown -), Read injury (n/a - Recovered/Resolved -), Read injury (n/a - Recove	EU-EC- 10012654374	07/06/2022	Spontaneous						Female	No	Blood pressure decreased	TOZINAMERAN	Not reported	ICSR
Healthcare (012655171) O7/06/2022 Spontaneous Healthcare (012655171) Frofessional European (2012655171) O7/06/2022 Spontaneous Healthcare (2012655171) Healthcare (2012655171) O7/06/2022 Spontaneous Healthcare (2012665171) Healthcare (2012665171) O7/06/2022 Spontaneous Healthcare (2012665171) Frofessional European (2012665171) OND (Altered state of (201206716)) Area (201216716) Not (201206716) Professional European (201206716) Area (201206716) Not reported (201206716) Not reported (201206716) Onderweed/Resolved - (201206716) Ond				Professional								immunisation - Not applicable - [n/a -		
U-EC-0012655171 O7/06/2022 Spontaneous Healthcare Rooneroffscasional European Economic Area O7/06/2022 Spontaneous Healthcare Rooneroffscasional European European European European European European European European Onter Medically Important Condition), Anaphylactic reseation (n/a - Recovered/Resolved - Undically Important Condition), Anaphylactic reseation (n/a - Recovered/Resolved - Other Medically Important Condition), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspneae (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspneae (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspneae (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspneae (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspneae (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspneae (n/a - Recovered/Resolved - Other Medically Important Condition), Heart rate increased (n/a - Recovered/Resolved - Other Medically Important Condition), Heart rate increased (n/a - Recovered/Resolved - Other Medically Important Condition)												.,,,		
Professional European Economic Area European Economic Area Specified Consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved -), Cyanosis (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Recovered/Resolved -) Depressed level of consciousness (n/a - Recovered/Resolved -) Professional European Economic Area European Condition), Blood pressure decreased (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),											Other Medically Important			
Condition), Anaphylactic reaction (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved -), Cyanosis (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),	EU-EC- 10012655171	07/06/2022	Spontaneous		European Economic				Female	No	consciousness (n/a - Recovered/Resolved -	[TOZINAMERAN] (S - COVID-19	Not reported	ICSR
- Recovered/Resolved - Life Threatening, Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved -), Cyanosis (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),											Condition),			
Blood pressure decreased (n/a - Recovered/Resolved -), Cyanosis (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),											- Recovered/Resolved - Life Threatening, Other Medically Important			
Cyanosis (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),											Blood pressure decreased (n/a - Recovered/Resolved			
Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),											Cyanosis (n/a -			
Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),											Depressed level of			
Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),											Recovered/Resolved - Other Medically Important			
Recovered/Resolved -), Grunting (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),														
Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -),														
Recovered/Resolved -),														
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										Hypotension (n/a - Recovered/Resolved -),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved -),			
										Pallor (n/a - Recovered/Resolved -),			
										Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Stridor (n/a - Recovered/Resolved -),			
										Tachycardia (n/a - Recovered/Resolved -),			
										Throat tightness (n/a - Recovered/Resolved -),			
										Use of accessory respiratory muscles (n/a - Recovered/Resolved -),			
EU-EC-	07/06/2022	Spontaneous	Hoaltheara	Non	Not	3-11	Not	Male	No	Wheezing (n/a - Recovered/Resolved -) Arthritis (n/a - Not	COMIRNATY	Not reported	ICSR
10012659037	07/00/2022	Sporttaneous		European Economic	available	Years	Specified	Male	INO	Recovered/Not Resolved -	[TOZINAMERAN] (S - COVID-19	Not reported	ICSK
				Area							immunisation - Not applicable - [n/a - n/a - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Hepatitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain (n/a - Not Recovered/Not Resolved -			
										Renal impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012659158	07/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
											applicable - [1d -		
										Alanine aminotransferase	applicable - [1d - .2mL - Intramuscular])		
										Alanine aminotransferase increased (n/a - Unknown	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood lactate dehydrogenase increased	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood sodium decreased	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), Creactive protein increased (n/a - Unknown increased (n/a - Unknown increased (n/a - Unknown -),	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), Blood uric acid decreased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), C-holangitis (n/a - Unknown -) Caused/Prolonged Hospitalisation, Other	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), Cholangitis (n/a - Unknown -), Cholangitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile convulsion (0d - Recovered/Resolved -	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), Cholangitis (n/a - Unknown -), Cholangitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile convulsion (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	applicable - [1d - .2mL -		
										Alanine aminotransferase increased (n/a - Unknown -), Aspartate aminotransferase increased (n/a - Unknown -), Blood bilirubin increased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), Blood sodium decreased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), C-reactive protein increased (n/a - Unknown -), Cholangitis (n/a - Unknown -), Cholangitis (n/a - Unknown -), Cholangitis (n/a - Unknown -), Febrile convulsion (0d - Recovered/Resolved - Caused/Prolonged	applicable - [1d - .2mL -		

										ing report			
EU-EC- 10012659161	07/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not	3-11 Years	Not Specified	Male	No	(n/a - Unknown -), Hepatic function abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mean cell haemoglobin concentration increased (n/a - Unknown -), Mean cell volume decreased (n/a - Unknown), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown -) Blood pressure decreased (n/a - Recovering/Resolving -), Hypotension (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pulse abnormal (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ALISMA PLANTAGO-AQUATICA SUBSP. ORIENTALE ROOT] (C - n/a - n/a - [n/a - n/a - Oral]), [ATRACTYLODES LANCEA ROOT] (C - n/a - n/a - [n/a - n/a - Oral]), [CINNAMOMUM CASSIA BARK] (C - n/a - n/a - [n/a - n/a - Oral]), [POLYPORUS UMBELLATUS] (C - n/a - n/a - [n/a - n/a - Oral]), [PORIAE COCOS SCLEROTIUM] (C - n/a - n/a - [n/a - n/a - Oral]),	ICSR
EU-EC- 10012660613	07/06/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved -		[RISPERIDONE] (C - n/a - n/a - [n/a - n/a - Oral]) Not reported	ICSR
				Economic Area	avariable		эрестеч			Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012661354	07/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Conjunctival hyperaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Conjunctivitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Erythema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Kawasaki's disease (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Keratitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Photophobia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012661839	07/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012662813	07/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Axillary pain (3d - Recovered/Resolved -), Chest pain (3d - Recovered/Resolved -), Ear pain (3d - Recovered/Resolved -), Malaise (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	07/06/2022	Spontaneous		European	Not	3-11	Child	Male	No	Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -) Angioedema (80d -	COMIRNATY	Not reported	ICSR
10012662828			Professional	Economic Area	available	Years				Recovering/Resolving - Other Medically Important Condition), Oedema peripheral (79d - Recovered/Resolved - Other Medically Important Condition), Swelling (79d - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10012644352	06/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012644796	06/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - 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- 10012645956	06/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012648678	06/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hospitalisation) Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012650208	06/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012651823	06/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Intestinal obstruction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012630740	03/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eczema herpeticum (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012633469	03/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Axillary mass (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Axillary pain (n/a - Recovered/Resolved - Disabling),	applicable - [1d - n/a - Intramuscular])		
										Lymphadenopathy (n/a - Recovered/Resolved - Disabling)			
EU-EC- 10012633898	03/06/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Axillary pain (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Vaccination site erythema (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site swelling (n/a - Recovering/Resolving - Other Medically Important			
EU-EC- 10012634014	03/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				7.11-02						Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - Intramuscular])		
										COVID-19 (n/a - Unknown - Other Medically Important Condition),			
										Constipation (n/a - Unknown -),			
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Nephrotic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rheumatic heart disease (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Swelling (n/a - Unknown -			
10012637117		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012638037	03/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012638458	03/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -), Pruritus (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Vaccination site reaction (0d - Recovered/Resolved			
EU-EC- 10012616626	02/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	-) Paraesthesia (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012616666	02/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012616780	02/06/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
										Headache (12d - Recovered/Resolved -	Intramuscular])		

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										Caused/Prolonged Hospitalisation),			
										Pyrexia (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
	20.40.6.40.00									Vomiting (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			1000
EU-EC- 10012616975	02/06/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eye pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Optic neuritis (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Caused/Prolonged Hospitalisation), Visual acuity reduced (n/a - Unknown - Caused/Prolonged			
EU-EC- 10012619377	02/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hospitalisation) Wheezing (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012624728	02/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (5d - Recovered/Resolved -), Vaccination site joint pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC-	02/06/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Male	No	(3d - Recovered/Resolved -) Vaccination site discomfort	applicable - [n/a - .2mL - Intramuscular]) COMIRNATY	Not reported	ICSR
10012626798			Professional		available	Years				(n/a - Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])		
EU-EC- 10012626810	02/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012626823	02/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain upper (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012627040	02/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012627078	02/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Glossodynia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012627079	02/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dependent rubor (n/a - Unknown -), Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012627113	02/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Malaise (n/a - Unknown -) Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypergammaglobulinaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Hypertransaminasaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Meningitis aseptic (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pleural effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Prothrombin level decreased (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			

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										Pyrexia (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Red blood cell sedimentation rate increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012606103	01/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Migraine (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012606149	01/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10012607136	01/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Appendicitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012607172		Spontaneous	Professional	Economic Area	Not available	3-11 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012607668		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fracture (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012607976	01/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fracture (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012612436	01/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dermatitis allergic (10d - Recovered/Resolved -), Erythema (10d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Lymphadenitis (10d - Recovered/Resolved -)			
EU-EC- 10012613051	01/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012615030	01/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	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- 10012615417	01/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain upper (n/a - Unknown -), Headache (n/a - Unknown -), Peripheral swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012615601	01/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012616391	01/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012594631	31/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hyperglycaemia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012595366	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypoglycaemia (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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EU-EC- 10012596380	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Bacterial infection (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012596451	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Angioedema (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012597145	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Cold sweat (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Cyanosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Depressed level of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Heart rate decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Moaning (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Oxygen saturation decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Respiratory rate decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
FILEC	21/05/2022	Sportores	Haalthaara	Non	Not	2,11	Not	Female	No	Slow response to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIDNATY	Not reported	ICCT
EU-EC-	31/05/2022	Spontaneous	nealthcare	Non	Not	3-11	Not	Female	No	Loss of consciousness	COMIRNATY	Not reported	ICSR

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10012597339			Professional	European Economic Area	available	Years	Specified			(25min - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012597656	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10012598047	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) Bacterial infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
EU-EC- 10012598302	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Kidney infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
EU-EC- 10012598804	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Endocarditis (n/a - Unknown - Other Medically Important Condition), Osteomyelitis (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012599073	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Important Condition) Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012600177	31/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012601184	31/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
EU-EC- 10012601733	31/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Middle ear inflammation (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10012602599	31/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Hypotension (n/a - Unknown -), Insomnia (n/a - Unknown -), Pruritus (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FLUTICASONE PROPIONATE] (C - Seasonal allergy - n/a - [10d - n/a - Nasal - More in ICSR]), [LEVOCETIRIZINE] (C - Seasonal allergy - n/a - [10d - n/a - Oral]), [TRANILAST] (C - Seasonal allergy - n/a - [10d - n/a - Ophthalmic - More in ICSR)]	ICSF
EU-EC- 10012604416	31/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	ICSR]) Not reported	ICSF
EU-EC- 10012604576	31/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSF
EU-EC- 10012604612	31/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSF
EU-EC- 10012604769	31/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10012604778	31/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cough (5d - Recovered/Resolved -), Pyrexia (5d - Recovered/Resolved -), Wheezing (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10012605554	31/05/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	Epilepsy (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19	[LORATADINE] (C - Rhinitis allergic - n/a - [n/a - n/a - Oral]),	ICSR

Fired Projection Projecti	J.11.2022 C	13.24							Run L	ne Li	sting Report			
Part											Febrile convulsion (n/a -	applicable - [1d - n/a	MONTELUKAST SODIUM] (C - Asthma	
March Marc														
											Recovered/Resolved - Other Medically Important			
BLEC 20/25/222 Spontamence Healthcare Professional Healthcare Professional Healthcare Professional Healthcare Hea		30/05/2022	Spontaneous	Healthcare	European Economic				Male	No	Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
											Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important			
ELECTION 2005/2022 Sprittaneous Healthcare Professional European		30/05/2022	Spontaneous	Healthcare	European Economic				Male	No	- Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
Professional European Area Professional European Area Area Profes		30/05/2022	Spontaneous		European Economic				Male	No	Appendicitis (n/a - Not Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
Recovered Recovered Application Applic		30/05/2022	Spontaneous		European Economic					No	Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-19	Not reported	ICSF
EU-EC- 1001259731 30/05/2022 Spontaneous Healthcare Room Room Recovered Reco					Alea						Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved - Other Medically Important	applicable - [n/a - 10ug -		
ELEC- 10012587313 30/05/2022 Spontaneous Healthcare Professional Carponanic Area Non Professional Carponanic Area Non European Charles Professional Carponanic Carponan											Sedation (n/a -			
EU-EC- 10012587313 Bell-ticze														
Professional European Economic Area Professional European Economic Reconomic Area Professional European Economic Reconomic Reconom											Recovering/Resolving -)			
Atrial fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myopericardiis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Resolved -), Tachycardia (n/a - Not Recovered/Not Not Recover		30/05/2022	Spontaneous		European Economic				Female	No	Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
Recovered/Not Resolved -), Myopericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved -), Product administered to patient of inappropriate age (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -), ToZINAMERAN] (S - COVID-19 Immunisation - Not applicable - [1d - n/a - Intramuscular]) EU-EC- 10012590265 EU-EC- 10012590265 Bone pain (7d - Recovered/Resolved -), Bone pain (7d -											Recovered/Not Resolved - Other Medically Important			
Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved -), Product administered to patient of inappropriate age (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Resolved -), ToZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) ToZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) EU-EC- Other Medically Important Condition) EU-EC- Other Medically Important Condition) EU-EC- Not Personal Economic available (Not Personal Economic Avail											Recovered/Not Resolved -			
Recovered/Not Resolved -											Recovered/Not Resolved - Other Medically Important			
EU-EC- 10012590265 Spontaneous Professional Professional Professional European Professional European Bulletare Professional European Bulletare Professional European Bulletare Professional European Bulletare Bulletare Bulletare Professional European Bulletare Bulletare Professional Professional Specified Professional Bulletare Professional Specified Professional Profe														
EU-EC- 10012590265 Spontaneous Non Healthcare Professional Healthcare European Not applicable - [1d - n/a - Intramuscular]) Not reported Specified											patient of inappropriate age (n/a - Not Recovered/Not Resolved -			
Healthcare Professional Area Professional Area Professional Professional Professional Professional Area Professional Area Professional Professional Area Professional Professi											Tachycardia (n/a - Not			
EU-EC- 10012593290 Spontaneous Healthcare Professional Economic available Recovered Resolved - Professional Recovered Resolved - Remains Recovered Resolved - Remains Recovered Resolved - Remains Recovered Resolved - Other Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition) List and Dizziness (61d - Recovered/Resolved - Nother Medically Important Condition)		30/05/2022	Spontaneous	Healthcare	Economic				Female	No	Recovered/Resolved -), Bone pain (7d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC- 10012593290 Spontaneous Healthcare Professional Economic available Years Condition Condit											Dizziness (61d - Recovered/Resolved -), Headache (2139h -			
10012593290 Professional Economic available Years	EU EC	20/05/2==	Const	Hac to	F	No. 5	2.4.	Char	F '	NI-	Other Medically Important Condition)	COMIDMAT	Net ner out 1	TOC
		30/05/2022	spontaneous		Economic			Cnila	remale	INO		[TOZINAMERAN] (S -	INOL reported	<u>ICSR</u>

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											immunisation - Not applicable - [1d -		
EU-EC- 10012593365	30/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Chest pain (1d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012593455	30/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Condition) Pyrexia (n/a - Unknown -), Vaccination site mass (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10012583614	29/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 10012584314	29/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Condition) Psoriasis (3d - Recovering/Resolving -)	- n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012569058	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fall (0d - Recovered/Resolved -), Loss of consciousness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Presyncope (0d - Recovered/Resolved -), Tremor (0d -			
EU-EC- 10012569527	27/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Recovered/Resolved -) Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Not Recovered/Not Resolved -			
										Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012569712	27/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dermatitis allergic (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Nasal discomfort (n/a - Unknown - Other Medically Important Condition),	- n/a])		
										Pruritus (2d - Recovered/Resolved - Other Medically Important Condition),			
										Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition),			
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Swelling face (3d - Recovered/Resolved - Other Medically Important Condition),			
										Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012570025	27/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Fall (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			i roressiUIId[Area						Malaise (n/a - Recovering/Resolving -),	immunisation - Not		

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										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10012570047	27/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (7d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012570098	27/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diabetic ketoacidosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Type 1 diabetes mellitus (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICS
EU-EC- 10012571490	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hospitalisation, Disabling) Erythema (n/a - Not Recovered/Not Resolved -), Pustule (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Vaccination site reaction (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012571684	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Chills (1d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Feeling hot (10min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [0d - .2mL - Intramuscular])	Not reported	ICSF
										Pyrexia (1d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)			
EU-EC- 10012572345	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Axillary mass (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [0d - .2mL - Intramuscular])	Not reported	ICSI
EU-EC- 10012573505	27/05/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10012573649	27/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSI
										Blood pressure ambulatory decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Depressed level of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Heart rate decreased (n/a - Unknown -), Oxygen saturation			
										decreased (n/a - Unknown -), Pallor (n/a - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10012574505	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Hospitalisation) Herpes zoster (7d - Recovered/Resolved -), Rash (7d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10012574542		Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Recovered/Resolved -) Dysphagia (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSI
100123/4342			Professional		avaliable	rears)	immunisation - n/a - [n/a - n/a - n/a]		
EU-EC- 10012574575	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			

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EU-EC- 10012574579	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cough (79d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Dizziness (85d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Fatigue (85d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Malaise (85d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10012574645	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012575470	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICSF
											COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10012575662 EU-EC-		Spontaneous	Healthcare Professional	European Economic Area	Not available Not	3-11 Years	Child	Female Female	No No	Alopecia (n/a - Unknown -) Myositis (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) COMIRNATY	Not reported Not reported	ICSF
10012577047		Spontaneous	Healthcare Professional	European Economic Area	available	Years				Recovered/Not Resolved -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])		
EU-EC- 10012577949	27/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSF</u>
EU-EC- 10012578846	27/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Nasopharyngitis (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved -			
EU-EC-	27/05/2022	Cnontonoous	Llogithenus	European	Not	2.11	Child	Male	No	Other Medically Important Condition)	COMIRNATY	Not reported	ICCI
10012578923	27/05/2022	Spontaneous	Professional	Economic Area	Not available	3-11 Years	Child	Маје	INO	Abdominal pain (3d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Pyrexia (3d - Recovered/Resolved -)	1{DF} - Unknown])		
EU-EC- 10012578934	27/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSF
EU-EC- 10012579786	27/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (5895min - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Legacters Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012560733	26/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Important Condition) Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug -	Not reported	ICSF
EU-EC- 10012561534	26/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	IIIrd nerve paralysis (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10012564943	26/05/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Pain in extremity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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			Professional	Area							COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012565178	26/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dyspnoea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012568085	26/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10012568143	26/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vision blurred (1d - Recovered/Resolved -)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - n/a - Intramuscular - More in ICSR])	Not reported	ICSF
EU-EC- 10012568575	26/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abnormal sensation in eye (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Anaphylactic reaction (865min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	,		
										Depressed level of consciousness (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dyspnoea (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Flushing (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Musculoskeletal discomfort (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Mutism (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Oropharyngeal discomfort (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Urticaria (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012549672	25/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (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
EU-EC- 10012550466	25/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Not Specified	No	Diarrhoea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012550508	25/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012552445	25/05/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Not Specified	No	Axillary pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Body temperature increased (n/a - Unknown	COVID-19 immunisation - Not applicable - [n/a -		

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										-), Lymph node pain (n/a -	.3mL - Intramuscular])		
										Unknown -), Lymphadenopathy (n/a -			
										Unknown -), Vaccination site reaction			
U-EC- 0012555908	25/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	(n/a - Unknown -) Vaccination site erythema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	Not reported	IC
U-EC-	25/05/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Dizziness (2h -	Intramuscular]) COMIRNATY	Not reported	IC
0012556116	,,			Economic	available	Years				Recovered/Resolved -), Hypoaesthesia (2h - Recovered/Resolved -), Nausea (2h - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
U-EC- 0012557146	25/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	10
										- Unknown -), Asthenia (n/a - Unknown -),	applicable - [1d - n/a - n/a])		
										Chest pain (n/a - Unknown -),			
										Cold sweat (n/a - Unknown -),			
										Palpitations (n/a - Unknown -),			
										Rash (n/a - Recovering/Resolving -),			
J-EC- 0012557155	25/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Tremor (n/a - Unknown -) Activated partial thromboplastin time abnormal (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[FOLIC ACID] (C - Thalassaemia minor - n/a - [n/a - n/a - Oral])]
										Contusion (n/a - Unknown -),	applicable - [n/a - n/a - Intramuscular])		
										Epistaxis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Gingival bleeding (n/a - Unknown -),			
										Haemorrhage (n/a - Unknown - Life Threatening, Other Medically Important Condition),			
										Petechiae (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Thrombocytopenia (n/a - Unknown - Life Threatening, Other Medically Important Condition)			
	25/05/2022	Spontaneous	Healthcare	Non	Not available	3-11 Years	Not	Female	No	Blood pressure decreased (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S -	Not reported	
012557896			Professional	Economic Area	available	rears	Specified			Medically Important Condition),	COVID-19 immunisation - Not		
0012557896			Professional	Economic	available	rears	Sреспеа			Medically Important	COVID-19		
012557896			Professional	Economic	avaijabie	rears	Specified			Medically Important Condition), Contusion (n/a - Unknown	COVID-19 immunisation - Not applicable - [1d - n/a		
01255/896			Professional	Economic	available	rears	Брестиеа			Medically Important Condition), Contusion (n/a - Unknown -),	COVID-19 immunisation - Not applicable - [1d - n/a		
01255/896			Professional	Economic	avanione	Icais	Брестеа			Medically Important Condition), Contusion (n/a - Unknown -), Fall (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mouth haemorrhage (n/a - Unknown -),	COVID-19 immunisation - Not applicable - [1d - n/a		
0012557896			Professional	Economic	avalibute	Cars	Specified			Medically Important Condition), Contusion (n/a - Unknown -), Fall (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mouth haemorrhage (n/a - Unknown -), Muscle spasms (n/a - Unknown -),	COVID-19 immunisation - Not applicable - [1d - n/a		
01255/896			Professional	Economic	avalibute	Cars	Specified			Medically Important Condition), Contusion (n/a - Unknown -), Fall (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mouth haemorrhage (n/a - Unknown -), Muscle spasms (n/a -	COVID-19 immunisation - Not applicable - [1d - n/a		
01255/896			Professional	Economic	avalibute	Cars	Specified			Medically Important Condition), Contusion (n/a - Unknown -), Fall (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mouth haemorrhage (n/a - Unknown -), Muscle spasms (n/a - Unknown -), Presyncope (n/a -	COVID-19 immunisation - Not applicable - [1d - n/a		

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										Tonic convulsion (n/a - Unknown - Other Medically Important Condition),			
										Tooth injury (n/a -			
ELLEC	25/05/2022	Chontanoous	Non	Europoan	Not	2 11	Child	Female	No	Unknown -)	COMIDNATY	Not reported	ICCD
EU-EC- 10012558158	25/05/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[n/a - 1{DF} - n/a])		
										Poor quality sleep (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10012558411	25/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Gait disturbance (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Muscular weakness (n/a - Recovered/Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012559448	25/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Acute abdomen (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Ascites (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Tenderness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										White blood cell count increased (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012536844	24/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash macular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012537465	24/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10012537668	24/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012538172	24/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Croup infectious (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
EU-EC-	24/05/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Male	No	Presyncope (0d -	- n/a]) COMIRNATY	Not reported	ICSR
10012539112	,		Professional		available	Years	Specified			Recovered/Resolved -	[TOZINAMERAN] (S - COVID-19		33/

				Economic Area						Other Medically Important Condition)	immunisation - Not applicable - [1d - .2mL -		
EU-EC- 10012539388	24/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Unknown -), Palpitations (n/a -	[Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
EU-EC- 10012539611	24/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Recovering/Resolving - Caused/Prolonged Hospitalisation) Ataxia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	IC
										Loss of consciousness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Retrograde amnesia (2d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
:U-EC- .0012539818	24/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	10
										Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	- Intramuscular])		
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
U-EC- 0012539946	24/05/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	Ī
U-EC- 0012540103	24/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY	Not reported	Ī
U-EC- 0012540943	24/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Application site pain (n/a - Unknown -), Arthralgia (n/a - Unknown -), Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	Ī
										Headache (n/a - Unknown -), Nausea (n/a - Unknown -)			
U-EC- 0012541535	24/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Appendicitis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<u> </u>
U-EC- 0012542631	24/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	Ī
U-EC- 0012543709	24/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (7d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u> </u>
										Chest pain (18d - Recovered/Resolved -),	applicable - [n/a - n/a - Intramuscular])		
										Chills (18d - Recovered/Resolved -),			
										Nausea (9d - Recovered/Resolved -),			
										Pericardial effusion (7d - Recovered/Resolved - Other Medically Important Condition),			
										Pericarditis (18d - Recovered/Resolved - Other Medically Important Condition)			
		Spontaneous		European	Not	3-11	Child	Male		Abdominal pain (n/a -	COMIRNATY	Not reported	I

											1{DF} -		
EU-EC-	24/05/2022	Spontaneous		European	Not	3-11	Child	Male	No	Immunisation reaction (1h	Intramuscular]) COMIRNATY	Not reported	ICSR
10012544499			Professional	Economic Area	available	Years				- Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10012544514	24/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Immunisation reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012545033	24/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Appendicitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10012546016	24/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Epilepsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Malaise (n/a - Recovering/Resolving -)			
EU-EC- 10012546950	24/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Food allergy (n/a - Unknown -), Throat tightness (n/a - Unknown -), Urticaria (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	24/05/2022	Spontaneous	Non	Non	Not	3-11	Not	Female	No)	COMIRNATY	Not reported	ICSR
10012548144			Healthcare Professional	European Economic Area	available	Years	Specified), Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Inflammation (n/a - Unknown -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Lip discolouration (n/a - Unknown -), Oxygen saturation abnormal (n/a - Not Recovered/Not Resolved -), Pallor (n/a - Unknown -),			
										Secretion discharge (n/a - Unknown -), Seizure (n/a - Unknown -			
										Other Medically Important Condition)			
EU-EC- 10012548215	24/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Kawasaki's disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10012548428	24/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Henoch-Schonlein purpura (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
EU-EC- 10012526112	23/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Dry skin (n/a - Unknown -),	immunisation - Not applicable - [1d - n/a - n/a])		
										Erythema (n/a - Unknown -),			
										Haemorrhage (n/a - Unknown - Other Medically Important Condition),			
										Kawasaki's disease (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	23/05/2022	Spontaneous	Non	Non	Not	3-11	Not	Female	No	Pain in extremity (n/a - Unknown -) Hypopnoea (n/a - Not	COMIRNATY	Not reported	ICSR
10012528198	<i>_J, JJ</i> 2022	Sportaneous	Healthcare Professional	European	available	Years	Specified	Tomale	140	Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not	not reported	ICSK

											applicable - [n/a - n/a - n/a])		
EU-EC- 10012528667	23/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Head injury (n/a - Unknown -), Loss of consciousness (10s	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR	Not reported	ICSF
										- Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)	INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not		
										Recovered/Resolved -)	applicable - [n/a - n/a - n/a])		
EU-EC- 10012531174	23/05/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
				Area						Blood pressure decreased (n/a - Fatal - Results in Death, Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - Intramuscular])	[DIMETHYL POLYSILOXANE (SILICONE ANTIFOAM AF9010),	
										Blood pressure immeasurable (n/a - Fatal - Results in Death, Other Medically Important Condition),		DIMETICONE] (C - n/a - n/a - [n/a - n/a - n/a]), [ETHYL LOFLAZEPATE]	
										Bradycardia (n/a - Fatal - Results in Death, Other Medically Important		(C - n/a - n/a - [n/a - n/a - n/a - n/a]), [ETIZOLAM] (C - n/a -	
										Condition), Cardiac failure acute (n/a -		n/a - [n/a - n/a - n/a]),	
										Fatal - Results in Death, Other Medically Important Condition),		[FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition),		[LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Cold sweat (n/a - Unknown -),		[LEVOCARNITINE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Cyanosis (n/a - Fatal - Results in Death, Other Medically Important Condition),		[NITRAZEPAM, NITRAZEPAM BP] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Fatigue (n/a - Unknown -),		[PHENOBARBITAL] (C - n/a - n/a - [n/a - n/a	
										Heart rate decreased (n/a - Fatal - Results in Death, Other Medically Important Condition),		- n/a]), [POTASSIUM ASPARTATE, POTASSIUM L-	
										Hyperhidrosis (n/a - Unknown -),		ASPARTATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Malaise (n/a - Unknown -),		[ZONISAMIDE] (C - n/a - n/a - [n/a - n/a -	
										Myocarditis (n/a - Fatal - Results in Death, Other Medically Important Condition),		n/a])	
										Palpitations (n/a - Unknown -),			
										Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Tachycardia (n/a - Unknown -)			
EU-EC- 10012531206	23/05/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Erythema (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Induration (n/a - Unknown -),	immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Mumps (n/a - Unknown -),			
										Parotid gland enlargement (n/a - Unknown -),			
										Staphylococcal abscess (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012531759	23/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012532835	23/05/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Not Specified	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
				Area						Painful respiration (n/a - Unknown - Caused/Prolonged	immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-	23/05/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Female	No	Hospitalisation) Gait disturbance (n/a -	TOZINAMERAN	Not reported	ICSR

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10012532862			Professional	European Economic Area	available	Years	Specified			Unknown -), Peripheral swelling (n/a - Unknown -), Pyrexia (n/a - Unknown -), Systemic lupus erythematosus (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10012532878	23/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown -), Dehydration (n/a - Recovered/Resolved - Other Medically Important Condition), Feeding disorder (n/a - Unknown - Other Medically Important Condition), Gastrointestinal disorder (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Unknown -), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Dermatitis atopic - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10012534867	23/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mg - Intramuscular])	Not reported	ICSR
EU-EC- 10012512225	20/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012512369	20/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Colour blindness acquired (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diplopia (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
EU-EC- 10012512563	20/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012515626	20/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fall (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 impunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012516503	20/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Overdose (n/a - Unknown - Other Medically Important Condition), Product preparation issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012517060	20/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012518315	20/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Petechiae (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012518712	20/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Gait disturbance (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Recovered/Not Resolved -),	applicable - [1d - n/a - n/a])		
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	.,,,,,		
										Hyporeflexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Not Recovered/Not Resolved -),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (3d - Recovered/Resolved -)			
EU-EC- 10012518802	20/05/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -),	COMIRNATY 10 MICROGRAMS/DOSE	Not reported	ICSR
			Professional				opesea			Feeling hot (n/a - Unknown -),	CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S -		
										Vision blurred (n/a - Unknown -)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10012520979	20/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC-	20/05/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Male	No	Allodynia (n/a - Unknown -	1{DF} - Unknown]) COMIRNATY	Not reported	ICSR
10012521493			Professional	Economic Area	available	Years), Capillaritis (n/a - Not Recovered/Not Resolved -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
), Dysaesthesia (n/a -	1{DF} - Intramuscular])		
										Unknown -), Increased tendency to			
										bruise (n/a - Unknown -), Pain of skin (n/a - Unknown -),			
										Rash (n/a - Unknown -)			
EU-EC- 10012521683	20/05/2022	Spontaneous	Healthcare Professional	Non	Not available	3-11 Years	Not Specified	Male	No	Neuralgia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Pain in extremity (30d - Recovered/Resolved - Caused/Prolonged	COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC-	19/05/2022	Spontaneous		European	Not	3-11	Not	Male	No	Hospitalisation) Asthenia (n/a -	COMIRNATY	[SALBUTAMOL	ICSR
10012499952			Professional	Economic Area	available	Years	Specified			Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 10ug -	SULFATE] (C - Asthma - n/a - [n/a - 100{DF} - Oral])	
										Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Gait disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Gastroenteritis (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Guillain-Barre syndrome			
										(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscle strength abnormal			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-		Spontaneous			Not	3-11	Not	Female	No	Chest discomfort (n/a -	COMIRNATY	Not reported	ICSR 31/5

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10012500622			Professional	European Economic Area	available	Years	Specified			Unknown -), Dyspnoea (n/a - Unknown -), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10012501192	19/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Altered state of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Aphonia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012501257	19/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Recovered/Resolved -) Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012502237	19/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012503553	19/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012504065	19/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hypersensitivity (60min - Recovered/Resolved -), Pharyngeal paraesthesia (60min - Recovered/Resolved -), Throat irritation (60min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - n/a])	Not reported	ICSR
EU-EC- 10012504159		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Blood creatine phosphokinase increased (n/a - Unknown -), Dermatomyositis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown -), Gait disturbance (n/a - Unknown -), Limb discomfort (n/a - Unknown -), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012504850	19/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10012506165		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Breakthrough COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Dehydration (n/a - Recovered/Resolved - Other Medically Important Condition), Oxygen saturation decreased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012506367		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved -), Myopericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012506641	19/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Tonic clonic movements (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Urinary incontinence (n/a - Unknown - Caused/Prolonged			
EU-EC- 10012507851	19/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Hospitalisation) COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	- Intramuscular - More in ICSR])		
EU-EC- 10012509702	19/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Immune thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Product administered to patient of inappropriate age (n/a - Unknown -)			
EU-EC- 10012490511	18/05/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Dehydration (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Gastritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012490993	18/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Breakthrough COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Pneumothorax (n/a - Unknown - Other Medically Important Condition),			
										Status epilepticus (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012491012	18/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10012491473	18/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012491775	18/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Lethargy (n/a - Unknown -), Pyrexia (n/a - Unknown -			
), Vaccine breakthrough			
EU-EC-	18/05/2022	Spontaneous	Non	Non	Not	3-11	Not	Male	No	infection (n/a - Unknown -) Myopericarditis (n/a - Not	TOZINAMERAN	Not reported	ICSR
10012492325			Healthcare Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	,	
EU-EC- 10012492345	18/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Feeling abnormal (n/a - Unknown -), Headache (n/a - Unknown	immunisation - Not applicable - [1d - n/a - n/a])		
										Loss of consciousness (n/a - Unknown - Other			
										Medically Important Condition), Syncope (0d -			
										Recovered/Resolved -			

										Other Medically Important Condition)			
EU-EC- 10012493978	18/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012495303	18/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eating disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Water pollution (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012496458	18/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Noninfective sialoadenitis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012496657	18/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash pruritic (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10012497735	18/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Acidosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Diabetes mellitus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetic ketoacidosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Mumps (n/a - Unknown - Caused/Prolonged Hospitalisation), Mumps (n/a - Unknown - Caused/Prolonged Hospitalisation), Volydipsia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vital functions abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Vital functions abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Unknown - Caused/Prolonged Hospitalisation),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012498579	18/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Caused/Prolonged Hospitalisation) Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id -	Not reported	ICSR
EU-EC- 10012498595	18/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cough (n/a - Unknown -), Odynophagia (n/a - Unknown -)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR

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1975 1975		18/05/2022	Spontaneous		Economic		Child	Male	No		[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
\$\$\text{\$\tex{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$\text{\$		18/05/2022	Spontaneous		Economic		Child	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL -	Not reported	ICSF
Miles Mile		18/05/2022	Spontaneous		Economic		Child	Male	No	(n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICS
17/95/2022 Sportseneous Healthcare County Count		18/05/2022	Spontaneous		Economic		Child	Female	No	Lip oedema (2d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
ELFEC. 10/15/2022 Sportaneous Non Realthcare (Duripean Professorial Section). ELFEC. 10/15/2022 Sportaneous Non Realthcare (Duripean Professorial Section). ELFEC. 10/15/2022 Sportaneous Non Realthcare (Duripean Professorial Section). ELFEC. 10/15/2022 Sportaneous Non Realthcare (Exporance Non Realthcare (Professorial Section)). ELFEC. 10/15/2022 Sportaneous Non Realthcare (Exporance Non Realthcare (Professorial Section)). ELFEC. 10/15/2022 Sportaneous Non Realthcare (Professorial Section). ELFEC. 10/15/2022 Sportaneous Non Realthcare (Professorial Section). Professorial Section Realthcare (Professorial Section). Professorial Realthcare (Professor		17/05/2022	Spontaneous		European Economic			Male	No	Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSI
EU-EC- 10012480080 17/05/2022 Spontaneous Rom Healthcare Professional Senome Residence Professio										- Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			
Important Condition, Private (n/a - Recovering/Resolving -), Vormiting (n/a - Not Recovering/Resolving -),		17/05/2022	Spontaneous	Healthcare	European Economic			Male	No	Abdominal pain (n/a - Recovered/Resolved -), COVID-19 (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
Healthcare Professional Area Professional Companies Professional Companies Professional Component Committee Professional Com										Important Condition), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a -			
EU-EC- 10012480262 Ty/05/2022 Spontaneous Healthcare Professional Economic Area Healthcare Professional European Economic Area Non European Economic Area Non European Economic Area Non European Economic Area Not Specified Female No Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nyalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered		17/05/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICS
Professional European Economic Area Professional Economic Area Professional European Economic Area Professional European Economic Area Professional European Economic Area Professional Eco										Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -), Pyrexia (n/a - Not			
Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a -		17/05/2022	Spontaneous		European Economic			Female	No	Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a -										Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Recovered/Resolved -			
										Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged			

										Caused/Prolonged Hospitalisation)			
	17/05/2022	Spontaneous		European	Not	3-11	Child	Male	No	Lymphadenopathy (3d -	COMIRNATY	Not reported	ICS
10012481030			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10012481358	17/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
-11.50	17/05/2022	C	1114	Non	Net	2.11	Net	NA-1-	NI-	Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a])	National	100
EU-EC- 10012481485	17/05/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>IC</u>
										Pyrexia (n/a - Recovering/Resolving -), Suspected COVID-19 (n/a	applicable - [1d - n/a - Intramuscular])		
										- Unknown - Other Medically Important Condition),			
EU-EC-	17/05/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Female	No	Vomiting (n/a - Recovering/Resolving -) Rheumatic heart disease	COMIRNATY	Not reported	ICS
10012482198		Spontanissas		European Economic Area	available	Years	Specified			(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012483384	17/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
										Malaise (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -			
EU-EC- 10012484614	17/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	IC
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10012485702	17/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Acute disseminated encephalomyelitis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	IC
	17/05/2022	Spontaneous		Non	Not	3-11	Not Specified	Female	No	Syncope (30min -	COMIRNATY	Not reported	IC
10012487231			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012487866	17/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	IC
EU-EC-	17/05/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Male	No) Chest pain (n/a -	applicable - [1d - 1{DF} - Unknown]) COMIRNATY	Not reported	ICS
10012488009	,,		Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Pericarditis (n/a - Recovered/Resolved -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		
	16/05/2022	Spontaneous		Non	Not	3-11	Not	Male	No	Other Medically Important Condition) Drug ineffective (n/a -	- n/a]) COMIRNATY	Not reported	ICS
10012466920			Healthcare Professional	European Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		
-11 50	16/05/2022	Caratana	Nan	Nan	Net	2.11	Net	Mala	NI-	- Unknown - Other Medically Important Condition)	- n/a - More in ICSR])	National	TO
EU-EC- 10012466971	10/05/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Dizziness (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>IC</u>
										Recovered/Resolved -), Feeling abnormal (n/a - Unknown -),	applicable - [1d - n/a - n/a])		
										Hypersensitivity (1d - Recovered/Resolved - Other Medically Important Condition),			
										Ocular hyperaemia (1d - Recovered/Resolved -),			
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										Rhinorrhoea (1d -			
										Recovered/Resolved -),			
										Sneezing (1d - Recovered/Resolved -)			
EU-EC- 10012466988	16/05/2022	Spontaneous	Healthcare	Non European	Not available	3-11 Years	Not Specified	Male	No	Blood glucose increased (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICS
			Professional	Economic Area						Diabetic ketoacidosis (n/a - Unknown -	COVID-19 immunisation - Not applicable - [1d - n/a		
										Caused/Prolonged Hospitalisation, Other	- Intramuscular])		
										Medically Important Condition),			
										Enuresis (n/a - Unknown -),			
										Increased appetite (n/a - Unknown -),			
										Type 1 diabetes mellitus (n/a - Not Recovered/Not			
										Resolved - Caused/Prolonged Hospitalisation, Disabling,			
										Other Medically Important Condition),			
										Weight decreased (n/a - Unknown -)			
EU-EC- 10012466997	16/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			Froressional	Area						Suspected COVID-19 (n/a	immunisation - Not applicable - [1d - n/a		
										- Unknown - Other Medically Important Condition)	- n/a])		
EU-EC- 10012473395	16/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
										Nausea (n/a - Not	- Intramuscular])		
										Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -			
EU-EC- 10012473620	16/05/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Child	Female	No	Axillary pain (15d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Lymphadenopathy (15d - Recovered/Resolved -),	COVID-19 immunisation - Not applicable - [1d -		
										Vaccination site pain (15d - Recovered/Resolved -)	.3mL - Intramuscular])		
EU-EC- 10012474968	16/05/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Female	No	Haemophagocytic lymphohistiocytosis (n/a -	COMIRNATY [TOZINAMERAN] (S -	[CAPTOPRIL] (C - Congestive	ICSR
				Area						Recovered/Resolved - Other Medically Important	COVID-19 immunisation - Not	cardiomyopathy - n/a - [n/a - 48mg - n/a]),	
										Condition)	applicable - [n/a - 1{DF} -	[DIGOXIN] (C -	
											Intramuscular])	Congestive cardiomyopathy - n/a - [n/a1mg - n/a]),	
												[FLUINDIONE] (C -	
												Congestive cardiomyopathy - n/a - [n/a - n/a - n/a]),	
												[FUROSEMIDE] (C -	
												Congestive cardiomyopathy - n/a - [n/a - 16mg - n/a])	
EU-EC- 10012475405	16/05/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area)	COVID-19 immunisation - Not		
											applicable - [1d - 1{DF} -		
EU-EC- 10012477008	16/05/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Vaccination site Iymphadenopathy (n/a -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
100127//008			Professional		available	icais				Recovering/Resolving -),	COVID-19 immunisation - Drug		
										Vaccination site pain (2d - Recovering/Resolving -)	withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10012477063	16/05/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Child	Female	No	Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area							COVID-19 immunisation - Not applicable - [1d -		
EU-EC-	16/05/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Vaccination site	1{DF} - Unknown]) COMIRNATY	Not reported	ICSR
10012477081	10,03,2022	opontaneous	Healthcare Professional	Economic	available	Years	Ciniu	Fide		lymphadenopathy (5d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19	not reported	<u></u>
											immunisation - Not applicable - [1d - n/a		
EU-EC-	16/05/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Lymphadenopathy (n/a -	- n/a]) COMIRNATY	Not reported	ICSR
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10012477112			Healthcare Professional	Economic Area	available	Years				Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular - More in ICSR])		
EU-EC- 10012477124	16/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Back pain (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -			
EU-EC- 10012466160	15/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Secondary tic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012465540	14/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved With Sequelae -), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved With Sequelae - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10012455217	13/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Pyrexia (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10012456756	13/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10012460044	13/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012461229	13/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition),	COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10012462453	13/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fall (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (n/a - Unknown - Other Medically Important Condition), Gait inability (n/a -	applicable - [1d - 10ug - Intramuscular])		
										Unknown - Other Medically Important Condition), Head injury (n/a -			
										Unknown - Other Medically Important Condition), Loss of consciousness (n/a			
										- Unknown - Other Medically Important Condition),			
										Seizure (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	13/05/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Female	No	Somnolence (n/a - Unknown - Other Medically Important Condition) Apraxia (7370min -	COMIRNATY	Not reported	ICSR
10012462463	. , –		Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Convulsion in childhood (7370min -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	·	
										Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Pyrexia (0d - Recovered/Resolved -), Tonic convulsion (7370min			
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										- Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10012462870	13/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Axillary pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
										Inflammation (n/a - Recovering/Resolving -)	immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012443823	12/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Body temperature abnormal (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSI
										Chest pain (n/a - Unknown - Other Medically Important Condition),			
										Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Epistaxis (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Hot flush (n/a - Unknown - Other Medically Important Condition),			
										Illness (n/a - Unknown - Other Medically Important Condition),			
										Insomnia (n/a - Unknown - Other Medically Important Condition),			
	12/05/2022						21.11			Nasal obstruction (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012444019	12/05/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10012445142	12/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
EU-EC-	12/05/2022	Spontaneous	Non	European	Not	3-11	Not	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -) Granulocyte count	COMIRNATY	Not reported	ICSF
10012445328	12/03/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Specified	remale		decreased (n/a - Unknown -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	1001
										Mean cell haemoglobin concentration decreased (n/a - Unknown -),	applicable - [1d - n/a - n/a])		
										Monocyte count increased (n/a - Unknown -), Neutrophil count			
										decreased (n/a - Unknown -), Pityriasis rosea (n/a -			
										Unknown -),			
EU-EC- 10012445383	12/05/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Rash (n/a - Unknown -) Fall (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
				Economic Area						Syncope (n/a - Recovering/Resolving -	COVID-19 immunisation - Not applicable - [1d - n/a		

EU-EC- 10012446470	43/05/2022									Tremor (n/a -			
	42/05/2022			1									
	12/05/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Recovering/Resolving -) Dry throat (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional							Erythema (n/a - Unknown -),	n/a - n/a - [n/a - n/a - n/a])		
										Pruritus (n/a - Unknown -),			
EU-EC- 10012447013	12/05/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	Rash (n/a - Unknown -) Adverse event following immunisation (n/a - Fatal -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Results in Death)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10012448066	12/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012448076	12/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (20d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012451713	12/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	Angina pectoris (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Back pain (n/a - Not Recovered/Not Resolved -),	Intramuscular])		
										Respiratory distress (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10012452169	12/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Malaise (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Pyrexia (n/a - Unknown -)	immunisation - Not applicable - [1d - 1{DF} - Unknown])		
EU-EC- 10012452221	12/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC-	12/05/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Male	No	Vaccination site	applicable - [1d - n/a - n/a]) COMIRNATY	Not reported	ICSR
10012452278	12,03,2022	Spontaneous	Professional	Economic Area	available	Years	Cima	Tidle		lymphadenopathy (n/a - Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Thor reported	10011
EU-EC- 10012452349	12/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Eyelid oedema (4d - Recovered/Resolved -), Hyperaemia (4d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC-	11/05/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Female	No	Recovered/Resolved -) Vaccination site pain (n/a -	applicable - [1d - n/a - n/a]) COMIRNATY	Not reported	ICSR
10012431701			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012431703	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012431706	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012431708	11/05/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Pyrexia (n/a - Recovered/Resolved -)	COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012431709	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC-	11/05/2022	Spontaneous		European	Not	3-11 Years	Not	Female	No	Vaccination site pain (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
10012431711			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012431713	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC-	11/05/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Female	No	Vaccination site pain (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR

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10012431715			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10012431718	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Localised oedema (n/a - Recovered/Resolved -), Pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012431732	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved -) Pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10012432556	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Seizure (n/a -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10012433129	11/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012433310	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (8d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	11/05/2022	Spontaneous		European	Not	3-11	Child	Male	No	Caused/Prolonged Hospitalisation) Abdominal pain (n/a - Recovered/Resolved -	COMIRNATY	Not reported	ICSR
10012434095			Professional	Economic Area	available	Years				Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012434577	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition), Eye movement disorder (n/a - Unknown -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vomiting (n/a - Unknown -			
EU-EC- 10012434675	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Blister (n/a - Recovering/Resolving - Other Medically Important Condition), Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition), Neuralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Pain of skin (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Condition), Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition), Rash erythematous (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10012434724	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) Dermatitis exfoliative generalised (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Drug eruption (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Erythema multiforme (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a -			
										Recovering/Resolving -), Rash (n/a -			
EU-EC-	11/05/2022	Spontaneous	Healthcaro	Non	Not	3-11	Not	Male	No	Recovering/Resolving -)	COMIRNATY	Not reported	ICCD
10012436959	11/05/2022	Sportaneous	Professional	Non European Economic Area	available	Years	Specified	male	INU	Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	not reported	ICSR
										Decreased appetite (n/a - Unknown -), Malaise (n/a - Unknown -),	- Intramuscular])		
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vaccination site pain (n/a - Unknown -),			
										Vomiting (n/a - Unknown -			
EU-EC- 10012436961	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Malaise (25min - Recovered/Resolved -), Syncope (15min - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
											applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012437038	11/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Grip strength decreased (n/a - Not Recovered/Not Resolved -), Hypoaesthesia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Not Resolved -), Neuropathy peripheral (n/a - Unknown - Other	n/a - Intramuscular])		
										Medically Important Condition)			
EU-EC- 10012437043	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012437127	11/05/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	Dizziness (33min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Syncope (33min - Recovered/Resolved - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012437723	11/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Heavy menstrual bleeding (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012437811	11/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Blister (n/a - Unknown -), Erythema (n/a - Unknown -), Herpes zoster (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	11/05/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Female	Yes	Pain (n/a - Unknown -) Arthralgia (n/a - Unknown	COMIRNATY	Not reported	ICSR
10012437915			Professional	Economic Area	available	Years				- Disabling),	[TOZINAMERAN] (S - COVID-19		

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EU-EC- .0012441285	11/05/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Recovered/Resolved - Other Medically Important	.2mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Condition), Fatigue (n/a - Recovered/Resolved -),	applicable - [n/a - n/a - Intramuscular])		
U-EC-	11/05/2022	Spontaneous	Healthcare	Non	Not	3-11	Not	Female	No	Presyncope (n/a - Recovered/Resolved -) Oedema peripheral (n/a -	COMIRNATY	Not reported	ICS
0012441357	,,		Professional	European Economic Area	available	Years	Specified			Unknown -), Peripheral swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
U-EC- 0012421061	10/05/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
J-EC- 0012422000	10/05/2022	Spontaneous	Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
				Area						Appendicitis (n/a - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
U.50	10/05/2022		1110	N	N	2.44	Note	l		Hand fracture (n/a - Recovered/Resolved -)	COMMUNITY	Notice	100
U-EC- 0012422435	10/05/2022	Spontaneous	Professional	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICS</u>
				Area						Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - Intramuscular])		
J-EC- 0012422998	10/05/2022	Spontaneous	Professional	Non European Economic	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
				Area						Decreased appetite (n/a - Recovered/Resolved -),	immunisation - Not applicable - [1d - n/a - n/a])		
										Diarrhoea (n/a - Recovered/Resolved -),	.,,=1)		
										Fatigue (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Pallor (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Tachycardia (n/a - Recovered/Resolved -),			
										Unresponsive to stimuli (n/a - Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0012423054	10/05/2022	Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cellulitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
U-EC- 0012423775	10/05/2022	Spontaneous		European Economic	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
			. 101033101101	, 11 001						Headache (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Urinary incontinence (n/a - Not Recovered/Not Resolved -)			
U-EC- 0012424118	10/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Nasopharyngitis (n/a - Not Recovered/Not Resolved -			

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EU-EC- 10012424416	10/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Other Medically Important Condition) Febrile convulsion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012425386	10/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10012425544	10/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Life Threatening), Cardiac failure (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012426603	10/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012427181	10/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved -), Vaccination site reaction (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012428280	10/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash maculo-papular (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012428351	10/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Unknown -), Photophobia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012429012		Spontaneous	Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	-	Not reported	ICSR
EU-EC- 10012430552		Spontaneous	Professional	Area	Not available	3-11 Years	Child	Male	No	Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012430554	10/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-	10/05/2022	Spontaneous	Healthcare	European	Not	3-11	Child	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY	Not reported	ICSR

10012430555	3.24		Professional	Economic Area	available	Years				sung Report	[TOZINAMERAN] (S - COVID-19 immunisation - Not		
EU-EC- 10012430557	10/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Unknown -),	applicable - [1d - 1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
				Area						Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	immunisation - Not applicable - [1d - 1{DF} - Unknown])		
EU-EC-	10/05/2022	Control	11-44	F	Net	3-11	Child	FI-	NI-	Vaccination site pain (n/a - Unknown -) Abdominal discomfort (n/a	COMIDNIATY	National	IC
10012430562	10/03/2022	Spontaneous		European Economic Area	Not available	Years	Cillia	Female	No	- Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	<u>IC</u>
EU-EC- 10012430638	10/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
EU-EC- 10012431044	10/05/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	IC
EU-EC- 10012410681	09/05/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
EU-EC- L0012413675	09/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	IC
										Pyrexia (n/a - Fatal - Results in Death), Seizure (n/a - Fatal -	- Intramuscular])		
										Results in Death), Vomiting (n/a - Fatal - Results in Death)			
EU-EC- 10012415670	09/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (1d - Recovered/Resolved -), Bundle branch block right	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	IC
				Area						(n/a - Unknown -), Chest pain (12450min - Recovered/Resolved -),	applicable - [n/a - n/a - Intramuscular])		
										Myocarditis (12450min - Recovered/Resolved - Other Medically Important Condition),			
										N-terminal prohormone brain natriuretic peptide increased (12450min - Recovered/Resolved -),			
EU-EC-	09/05/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Male	No	Pyrexia (10400min - Recovered/Resolved -) COVID-19 (n/a -	COMIRNATY	Not reported	IC
10012415697			Professional	Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	·	
										Recovered/Resolved - Other Medically Important Condition)	-		
U-EC- 0012416237	09/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Application site pain (n/a - Recovered/Resolved -), Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	IC
										Headache (n/a - Unknown -), Oropharyngeal pain (n/a -			
										Unknown -), Pyrexia (n/a - Unknown -)			
EU-EC- 10012416950	09/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Asthenia (0d - Not Recovered/Not Resolved -),	COMIRNATY 10 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19	Not reported	<u>IC</u>
			1	I .	1	1	1	1	1	Asthenia (0d -	immunisation - Not	I .	

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										Dizziness (0d - Recovered/Resolved -),			
										Nausea (0d - Not Recovered/Not Resolved -			
EU-EC- 10012417189	09/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pityriasis rosea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012419416	09/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012395326		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012399714	06/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Axillary pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012401623	06/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012403435	06/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Conjunctival hyperaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Multi-organ disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Multi-organ disorder (n/a - Caused/Prolonged Hospitalisation), Multisystem inflammatory	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
										syndrome in children (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012403443	06/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012403742		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	Arrhythmia (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012382506	05/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Application site pain (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	05/05/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Pyrexia (n/a - Unknown -) Application site pain (n/a -	COMIRNATY	Not reported	ICSR

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10012382760			Healthcare Professional		available	Years				Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10012385160	05/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Headache (1d - Recovered/Resolved -), Product administered to patient of inappropriate age (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10012389515	05/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Synovitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012391570	05/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012391881	05/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Chest pain (1h - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (1h - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - .3mg - Intramuscular])	Not reported	ICSR
EU-EC- 10012393080	05/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Other Medically Important Condition) Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012393162	05/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Eyelid oedema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10012393169	05/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lip oedema (7d - Recovered/Resolved -), Urticaria (7d - Recovered/Resolved -)	[Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012393190	05/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012393253	05/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Important Condition) Cough (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012371195	04/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Decreased appetite (3d - Recovered/Resolved -), Hallucination (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012371545	04/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

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										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	.1mL - Intramuscular])		
										Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vertigo (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012371565	04/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Migraine (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012372109	04/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Dyspareunia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Recovered/Resolved -), Electrocardiogram abnormal (n/a -	applicable - [1d - n/a - n/a])		
										Recovered/Resolved -), Palpitations (n/a - Recovered/Resolved -),			
										Pericarditis (n/a - Recovered/Resolved - Other Medically Important			
										Condition), Skin discolouration (n/a - Recovered/Resolved -)			
EU-EC- 10012372158	04/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Vomiting (n/a - Recovering/Resolving -)	- Intramuscular])		
EU-EC- 10012372205	04/05/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	applicable - [1d - n/a - Intramuscular])		
EU-EC- 10012372795	04/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Decreased appetite (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Febrile convulsion (n/a - Unknown - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - Intramuscular])		
EU-EC-	04/05/2022	Spontaneous	Non	Non	Not	3-11	Not	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -) Body temperature (2d -	COMIRNATY	Not reported	ICCI
10012373091	04/03/2022	Sportaneous	Healthcare Professional	Non European Economic Area	Not available	Years	Not Specified	remale	INO	Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Condition aggravated (n/a - Unknown - Other Medically Important Condition),	- n/a])		
										Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012373212	04/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - Intramuscular])		
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										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pallor (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012373224	04/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10012373312	04/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012376950	04/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pain in extremity (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012377001	04/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Autoimmune haemolytic anaemia (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Haemoglobin decreased (n/a - Recovering/Resolving -)			
EU-EC- 10012377353	04/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012377471	04/05/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Face oedema (3d - Recovered/Resolved -), Pruritus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012377961	04/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition), Rash pruritic (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012378121	04/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Condition) Near drowning (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
10012378859	04/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (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- 10012379220	04/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenitis (13d - Recovered/Resolved -), Vaccination site pain (13d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012379343	04/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash vesicular (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012379743	04/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Cardio-respiratory arrest (1d - Fatal - Results in Death), Myocarditis (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	[BILASTINE] (C - Rhinitis allergic - Not applicable - [n/a - n/a - n/a])	ICSR
EU-EC- 10012380202	04/05/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	3-11 Years	Not Specified	Female	No	Dyspnoea (6h - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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										Recovered/Resolved - Caused/Prolonged Hospitalisation),	- Intramuscular - More in ICSR])		
										Pyrexia (4h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash (45h - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012381485	04/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pityriasis rosea (99d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10012381502	04/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Hospitalisation), Visual impairment (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012381532	04/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10012381542	04/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Decreased appetite (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -), Somnolence (4d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012363303	03/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved -) Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012365933	03/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EII EC	03/05/2022	Chartenasus	Llogithopyo	Non	Not	2.11	Not	Malo	No	Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIDNATY	Not reported	ICCD
EU-EC- 10012365960	03/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Pallor (n/a - Recovering/Resolving -			
										Caused/Prolonged Hospitalisation), Vomiting (n/a -			
EU-EC-	03/05/2022	Spontaneous		Non	Not	3-11	Not	Male	No	Recovering/Resolving - Caused/Prolonged Hospitalisation) Dizziness (n/a -	COMIRNATY	Not reported	ICSR
10012366192			Professional	European Economic Area	available	Years	Specified			Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										- Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	,		
EU-EC- 10012366222	03/05/2022	Spontaneous	Healthcare Professional	Non European	Not available	3-11 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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				Economic Area						Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10012366862	03/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Gingivitis (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10012367254	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Fatigue (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
EU-EC- 10012367529 03/05/202	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Paraesthesia (n/a - Not Recovered/Not Resolved -)	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012368269	03/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Haematoma (n/a - Recovered/Resolved -), Skin abrasion (n/a - Recovered/Resolved -), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012369191	03/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved -) Abdominal pain upper (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Inappropriate schedule of product administration (n/a - Unknown -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012369202	03/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pallor (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012370085	03/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012370095	03/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site induration (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012370487	03/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012370501	03/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - Not applicable - [110d - n/a - n/a]), [RISPERIDONE] (C - Attention deficit hyperactivity disorder -	

												Not applicable - [132d - n/a - n/a])	
EU-EC- 10012370555	03/05/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Not Specified	No	Abdominal pain (n/a - Unknown -), Chills (n/a - Unknown -), Headache (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10012352604	02/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (n/a - Recovering/Resolving -), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012354793	02/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	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	ICS
EU-EC- 10012356048	02/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest discomfort (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d2mL - Intramuscular])	Not reported	ICSF
EU-EC- 10012359072	02/05/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Migraine (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine with aura (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	ICSF
EU-EC- 10012359150	02/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	ICSR
EU-EC- 10012360163	02/05/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Hyperthermia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[BAKUMONDOTO, GINSENG, OPHIOPOGONIS RADIX, PINELLIA] (C - Asthma - n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST, SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a]), [TIPEPIDINE HIBENZATE] (C - Asthma - n/a - [n/a - 3{DF} - n/a]), [TULOBUTEROL, TULOBUTEROL, TULOBUTEROL HYDROCHLORIDE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10012350525	01/05/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	n/a - n/a]) Not reported	ICSR
EU-EC- 10012338821	29/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash pruritic (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012339574	29/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Migraine (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - n/a])	Not reported	ICSR
EU-EC- 10012341368	29/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Pyrexia (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10012342817	29/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012343355	29/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [n/a - n/a - n/a]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10012343844	29/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Vaccination site reaction (n/a - Recovered/Resolved	Intramuscular])		
EU-EC- 10012344153	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Malaise (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
EU-EC- 10012344191	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Genital swelling (1d - Recovered/Resolved -), Swelling of eyelid (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Urticaria (1d - Recovered/Resolved -)	10ug - Intramuscular])		
EU-EC- 10012344266	29/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Bladder pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Constipation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Dysuria (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10012344304	29/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10012344441	29/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation, Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Medically Important Condition), Jaundice (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Transaminases abnormal (n/a - Unknown - Caused/Prolonged			
EU-EC- 10012346070	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Hospitalisation) Chills (1d - Recovered/Resolved -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)			
EU-EC- 10012346108	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Blister (7d - Recovered/Resolved -), Rash (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012346112	29/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (0d - Recovered/Resolved -), Fatigue (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Limb discomfort (0d - Recovered/Resolved -)			

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EU-EC- 10012346117	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012346455	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Tachycardia (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012346466	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cardiovascular disorder (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Herpes simplex (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10012346470	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (45d - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012346498	29/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Movement disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10012347683	29/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Arrhythmia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										COVID-19 (n/a - Recovered/Resolved -), Cardiogenic shock (n/a -			
										Unknown - Other Medically Important Condition),			
										Jaundice (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically			
EU-EC- 10012322798	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Important Condition) Urticaria (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10012322808	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving -), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
EU-EC-	28/04/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Male	No	Recovering/Resolving -) Autoimmune hepatitis (n/a	[n/a2mL - Intramuscular]) COMIRNATY	Not reported	ICSR
10012322969			Professional	Economic Area	available	Years	Specified			- Recovered/Resolved With Sequelae - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	·	
EU-EC- 10012322989	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	<u>ICSR</u>
EU-EC- 10012323018	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Headache (3d - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10012324198	28/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cellulitis (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012325428	28/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No) Diarrhoea (n/a - Unknown - Other Medically Important Condition), Gastroenteritis viral (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

										Other Medically Important			
EU-EC- 10012326069	28/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) Therapeutic response unexpected (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC- 10012326907	28/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Abdominal pain lower (n/a - Unknown -),	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
										Neck pain (n/a - Unknown -)	[n/a - n/a - Intramuscular])		
EU-EC- 10012327057	28/04/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Not Specified	Male	No	Chest discomfort (45min - Recovered/Resolved -), Dyspnoea (45min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
EU-EC- 10012328418	28/04/2022	Spontaneous		Non European	Not available	3-11 Years	Not Specified	Male	No	Recovered/Resolved -) Asthma (n/a - Unknown -).	applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
				Economic Area						Nasopharyngitis (n/a - Unknown -),	COVID-19 immunisation - Not applicable - [n/a -		
										Pyrexia (n/a - Unknown -),	n/a - Intramuscular])		
										Systemic viral infection (n/a - Unknown - Other Medically Important Condition),			
										Upper respiratory tract infection (n/a - Unknown -)			
EU-EC- 10012329028	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10012329634	28/04/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
										Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	- Intramuscular])		
EU-EC- 10012330968	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (14d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported I	ICS
				,						Hypophagia (14d - Recovered/Resolved -),	[n/a - 2{DF} - n/a])		
										Hypotonia (14d - Recovered/Resolved -), Nausea (14d -			
										Recovered/Resolved -), Weight decreased (14d -)	
EU-EC- 10012331319	28/04/2022	Spontaneous		Non European	Not available	3-11 Years	Not Specified	Female	No	Recovered/Resolved -) Depressed level of consciousness (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
				Economic Area			'			Unknown - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a		
										Dizziness postural (n/a - Unknown - Other Medically Important Condition),	- n/a])		
										Pallor (n/a - Unknown - Other Medically Important Condition),			
										Seizure (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10012331845	28/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Noninfective sialoadenitis (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10012332884	28/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Petechiae (26d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10012334417	28/04/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[HYDROCORTISONE BUTYRATE] (C - n/a - n/a - [n/a - n/a - Cutaneous]), [KETOCONAZOLE, KETOCONAZOLE PH. EUR.] (C - n/a - n/a - [n/a - n/a -	ICS
	27/04/2022	Spontaneous		European	Not	3-11	Not	Male	No	Headache (13d -	COMIRNATY	Cutaneous]) Not reported	ICS
10012310131			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19		

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										Nystagmus (13d - Recovered/Resolved -),	immunisation - n/a - [n/a3mL - Intramuscular])		
										Vertigo (13d - Recovered/Resolved -)			
EU-EC- 10012310676	27/04/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dehydration (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10012311858	27/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Erythema (n/a - Recovering/Resolving -), Localised oedema (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pain in extremity (n/a - Recovering/Resolving -)			
EU-EC- 10012312931	27/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Male	No	Influenza like illness (14d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10012313046	27/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Hypertrophic cardiomyopathy (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- 10012313560	27/04/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eye swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY 10 MICROGRAMS/JOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10012314129	27/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Condition) Drug ineffective (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown -), Suspected COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
										Medically Important Condition)			
EU-EC- 10012314161		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Synovitis (32d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10012314512	27/04/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eating disorder (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important			
EU-EC- 10012316462	27/04/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Condition) Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
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