Line Listing Report Time run: 30/11/2022 12:33:34

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10009775117	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Meningitis aseptic (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009775366	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009775377	24/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved -), Influenza like illness (n/a - Recovered/Resolved -), Vaccination site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
										(4d - Recovered/Resolved -)			
EU-EC- 10009775393	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009775710	24/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Resolved - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009775735	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1{DF} - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
EU-EC- 10009775743	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-), Influenza like illness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009775843	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving -) Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009775911	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR

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10009775928			Healthcare Professional		available	Years				Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])		
EU-EC- 10009775951	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tonsillitis (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009775956	24/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (3wk - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10009776059	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (6d - Recovered/Resolved -), Polymenorrhoea (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009776294	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza like illness (n/a - Recovering/Resolving -), Mobility decreased (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009776589	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injected limb mobility decreased (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Malaise (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009776626	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pain of skin (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009776636	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rhinorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009777786	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Feeling hot (2d - Recovering/Resolving -), Headache (2d - Recovering/Resolving	COMIRNATY	Not reported	ICSR
EU-EC- 10009777842	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR

										Recovered/Resolved			
EU-EC- 10009777949	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Dyspnoea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC-	24/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation) Haematuria (1d -	COMIRNATY	Not reported	ICSR
10009778169	_ ,,,		Healthcare Professional	Economic	available	Years				Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10009778415	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY	Not reported	ICSR
											[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10009778532	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthma (n/a - Recovered/Resolved - Life Threatening), Cyanosis (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovered/Resolved -), Wheezing (n/a - Recovered/Resolved			
EU-EC- 10009779084	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Vaccination site erythema (3d - Recovered/Resolved -), Vaccination site induration (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
										Vaccination site pruritus (n/a - Recovered/Resolved -)			
EU-EC- 10009779095	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009779107	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bradycardia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Hypotension (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009779113	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site lymphadenopathy (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009779141	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009779204	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

											1{DF} - Intramuscular])		
EU-EC- 10009779229	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009779352	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anxiety (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Respiratory distress (n/a - Recovering/Resolving - Other Medically Important Condition), Sensation of foreign body (n/a - Recovering/Resolving -), Tachycardia (n/a - Recovering/Resolving -), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Subcutaneous - More in ICSR])	Not reported	ICSR
EU-EC- 10009779409	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Obsessive- compulsive disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009779467	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rectal haemorrhage (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009779619		Spontaneous	Professional	Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -), Verification (1d - Recovered/Resolved -), Feeling cold (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009779979	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (n/a - Unknown -), Hypothermia (n/a - Unknown - Other Medically Important Condition), Musculoskeletal chest pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009780083	24/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Unknown -) Rash (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	COMIRNATY [TOZINAMERAN] (C -	ICSR

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			Professional	Area						Resolved - Caused/Prolonged Hospitalisation)	Immunisation - n/a - [n/a - 2{DF} - n/a])	Immunisation - n/a - [n/a - 1{DF} - n/a])	
EU-EC- 10009780258	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10009780285	24/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Encephalitis (7d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10009754745	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10009755261	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved -), Heavy menstrual bleeding (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICS
										-), Menstruation irregular (n/a - Recovered/Resolved -)			
EU-EC- 10009756337	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Other Medically Important Condition)			
EU-EC- 10009756556	23/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10009756857	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Tachycardia (1d - Recovered/Resolved -), Vomiting (1d -			
EU-EC- 10009756864	23/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adult	Male	No	Recovered/Resolved -) Arthralgia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
			Professional	Area						Chills (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Diarrhoea (n/a - Not Recovered/Not Resolved -), Fatique (n/a -			
										Recovering/Resolving -), Malaise (3d - Recovered/Resolved			
										Myalgia (2d - Recovered/Resolved -),			
										Nausea (n/a - Recovering/Resolving -)			
EU-EC- 10009757270	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[ASCORBIC ACID, PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Recovering/Resolving -),	1{DF} - n/a])		

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										-), Nausea (2d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved			
EU-EC- 10009757425	23/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Fatigue (1d - Recovered/Resolved -), Hallucination (350h - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -), Pain in extremity (1d			
										Recovered/Resolved -), Paranoia (350h - Recovered/Resolved			
EU-EC- 10009757465	23/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Anxiety (n/a - Unknown -), Blood pressure diastolic increased (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
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate increased (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009757738	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiovascular disorder (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pericarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009757750	23/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebral artery occlusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]),	Not reported	ICSR
										Retinal artery occlusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	[ETHINYLESTRADIOL, LEVONORGESTREL] (S - Contraception - Unknown - [n/a - 1{DF} - Oral])		
EU-EC- 10009758055	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009759141	23/08/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S -	[PARACETAMOL] (C - Oral surgery - n/a -	<u>ICSR</u>

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			Professional	Economic Area						- Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a	[n/a - n/a - n/a])	
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	- n/a])		
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tremor (n/a - Recovering/Resolving - Other Medically Important Condition),			
FILEG	22/00/2024		New	None	N-4	12.17	Note	Mala	N	Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOTINAMEDAN		TOOD
EU-EC- 10009759502	23/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Headache (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Illness (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)			
EU-EC- 10009759893	23/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Cardiac flutter (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Unknown - Other Medically Important Condition),	,,,,,		
										Palpitations (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009760371	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site movement impairment (n/a - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Vaccination site pain (n/a - Recovering/Resolving - Disabling)			
EU-EC- 10009760522	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Headache (n/a - Recovering/Resolving -), Injection site	applicable - [n/a - 1{DF} - n/a])		
										inflammation (n/a - Unknown -), Injection site pain			
										(n/a - Unknown -), Injection site swelling (n/a -			
										Unknown -),			

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										Malaise (n/a - Recovering/Resolving -),			
										Vomiting (2d - Recovered/Resolved			
EU-EC- 10009760585	23/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sleep disorder (n/a - Not Recovered/Not Resolved -),			
										Speech disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Visual impairment (n/a - Not Recovered/Not Resolved - Disabling),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009760796	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Chest pain (n/a - Recovered/Resolved -),	applicable - [n/a - n/a - n/a])		
										Cold sweat (n/a - Recovered/Resolved			
EU-EC- 10009760972	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Influenza like illness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10009761105	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009761122	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	.3mL - Intramuscular])		
EU-EC- 10009761124	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Retinal detachment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL -	Not reported	ICSR
										Visual field defect (n/a - Not Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10009761137	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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										Medically Important Condition)	immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])		
EU-EC- 10009761169	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (2d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Diarrhoea (2d - Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved -),			
										Rash papular (2d - Recovered/Resolved -), Vomiting (2d -			
										Recovered/Resolved			
EU-EC- 10009761175	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009761382	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (48h - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										Pyrexia (48h - Not Recovered/Not Resolved - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10009761496	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009761551	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovering/Resolving -), Nausea (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10009761553	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009761560	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Influenza like illness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009761575	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009761679	23/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Hypersensitivity (n/a	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Recovering/Resolving -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009761712	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oedema mouth (1d - Recovered/Resolved -), Vaccination site oedema (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009761733	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Diarrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC-	23/08/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Presyncope (1h -	Intramuscular]) COMIRNATY	Not reported	ICSR

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10009761735			Professional	Economic Area	available	Years				Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009761736	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009761739	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Testicular pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009762078	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009762148	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009762213	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Body temperature increased (2d - Recovered/Resolved -), Chest discomfort (1d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Injection site warmth (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -) Estima (2d - Recovered/Resolved -) Fatigue (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - Type IIa hyperlipidaemia - Dose not changed - [n/a - 40mg - n/a])	ICSR
EU-EC- 10009763413		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Fatigue (8d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009763431	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764088	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (18h - Recovered/Resolved -), Chest pain (18h - Recovered/Resolved -), Febrile convulsion (18h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR

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									Hallucination (18h - Recovered/Resolved -),			
									Headache (18h - Recovered/Resolved			
									Hyperhidrosis (18h - Recovered/Resolved			
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										applicable - [n/a -		
									Headache (n/a - Recovering/Resolving			
									Malaise (n/a - Recovering/Resolving			
									Pyrexia (n/a - Not Recovered/Not			
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Menstrual disorder (n/a - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
23/08/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (16d -	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
		FTOTESSIONAL	Alea						-), Peripheral swelling	[n/a - n/a - n/a])		
									Recovered/Resolved			
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Peripheral swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
23/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
									Fatigue (n/a - Recovering/Resolving	[n/a - n/a - n/a])		
									Influenza (n/a - Recovering/Resolving			
									Injection site pain (n/a - Not			
22/09/2021	Chontangous	Non	Europoan	Not	12 17	Adoloscopt	Malo	No	Resolved -)	COMIDNATY	Not reported	ICCD
23/08/2021	Spontaneous	Healthcare	Economic	available	Years	Adolescent	Маїе	INO	(n/a - Recovered/Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
									Dizziness (n/a - Recovered/Resolved -),			
									Feeling hot (1d - Recovered/Resolved -),			
									Headache (n/a - Recovered/Resolved -),			
	23/08/2021 23/08/2021 23/08/2021 23/08/2021 23/08/2021 23/08/2021 23/08/2021 23/08/2021	23/08/2021 Spontaneous	23/08/2021 Spontaneous Non Healthcare Professional Spontaneous Non Healthcare Professi	23/08/2021 Spontaneous Non Healthcare Professional Area 23/08/2021 Spontaneous Non Healthcare Professional Seconomic Area	23/08/2021 Spontaneous Non Healthcare Professional Reconomic Area Not European Healthcare Professional Reconomic Area Non Healthcare Professional Reconomic Area Not Healthcare Professional Reconomic Reconomic Area Non Healthcare Professional Reconomic Reconomic Area Not Healthcare Professional Reconomic Reconomic Area Non Healthcare Professional Reconomic Reco	23/08/2021 Spontaneous Non Healthcare Professional Reconomic Profess	23/08/2021 Spontaneous Non Healthcare Professional Realthcare Professional Area Professional Area Professional Professional Area Professional Area Professional Professional Area Professional Professional Area Professional Professional Professional Professional Professional Professional Professional Professional Professional Profession	23/08/2021 Spontaneous Non Healthcare Professional Professional Realthcare Recommit Realthcare Professional Realthcare Realthcare Recommit Realthcare Realthcare Recommit Realthcare Recommit Realthcare Recommit Realthcare Realthcare Recommit Realthcare Recommit Realthcare Recommit Realthcare Recommit Realthcare Recommit Realthcare Realthcare Recommit Realthcare Realthcare Recommit Realthc	23/08/2021 Spontaneous Non Healthcare Professional Realthcare Professional Rea	Spontaneous Non Healthcare Non Professional Area Not Professional Area	Professional Pro	Language Language

										Myalgia (1d - Recovered/Resolved			
EU-EC- 10009764465	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Dizziness (0d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Illusion (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764466	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Eye pruritus (5d - Recovered/Resolved -), Nasal congestion (5d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764468	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Resolved -) Micturition urgency (10d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10009764469	23/08/2021	Spontaneous	Non Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Recovered/Resolved -)	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764557	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009764576		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (30d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764577	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown -), Headache (27d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10009764583	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown -) Menstrual disorder (20d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764585	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Recovering/Resolving -), Pain in extremity (n/a - Not Recovered/Not	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764588	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Diarrhoea (0d - Recovered/Resolved -), Dizziness (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764589	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Diarrhoea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764591	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009764594	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal discomfort (2d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	23/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	-) Menstrual disorder	COMIRNATY	Not reported	ICSR

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10009764596			Healthcare Professional	Economic Area	available	Years				(n/a - Unknown -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10009764599	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Circulatory collapse (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009764601	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009764602	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -), Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Tachycardia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSE
EU-EC- 10009764604	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009764605	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (48d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009764607		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009764625	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Micturition urgency (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009764941	23/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009766098	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hodgkin's disease (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009766257	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (3d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009766261	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Balance disorder (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009766264	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -), Diarrhoea (0d - Recovering/Resolving -), Headache (0d - Recovering/Resolving -), Injection site pain (1d - Recovering/Resolving -), Limb discomfort (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009766270	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (44d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC-	23/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Syncope (0d -	COMIRNATY	Not reported	ICSR

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10009766276 EU-EC-	23/08/2021	Spontaneous	Professional	European	Not	Years	Adolescent	Male	No	Recovered/Resolved - Other Medically Important Condition) Swelling face (n/a -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY	Not reported	ICSR
10009766278			Healthcare Professional		available	Years				Unknown -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10009766281	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009766282	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009766284	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ageusia (1d - Unknown -), Fatigue (4d - Recovering/Resolving -), Headache (2d - Recovered/Resolved -), Influenza (3d - Not Recovered/Not Resolved -), Injection site pain	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										(2d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved			
										-), Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 10009766285	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	23/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Fomalo	No	-), Injection site erythema (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovering/Resolving -), Malaise (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -) Chills (6d -	COMIRNATY	Not reported	ICSD
10009766288	23/08/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Adolescent	remaie	NO	Chilis (6a - Recovered/Resolved -), Injection site erythema (9d - Recovered/Resolved -), Injection site pain (10d - Recovering/Resolving -), Injection site swelling (6d - Recovering/Resolving -), Lymphadenopathy (n/a - Unknown -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009766292		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Circulatory collapse (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009766297	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Genital herpes (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009766307	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
'				1						Important Condition)	[[.,, a .,, a .,, a])		1

			1			I				Recovered/Not	Immunisation - n/a -		
EU-EC-	23/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Resolved -) Urticaria (64d -	[n/a - n/a - n/a]) COMIRNATY	Not reported	ICSR
10009766317		эролгангоодо	Healthcare Professional	Economic	available	Years				Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		2001
EU-EC- 10009766318	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tinnitus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009766319	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10009766322	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Taste disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSF
EU-EC- 10009766330	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009766420	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Menstrual disorder (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10009766590	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Menstrual disorder (n/a - Unknown -)	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009766592	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (0d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009766627	23/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Body temperature increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site haematoma (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ARIPIPRAZOLE - TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - [n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE] (C - n/a - n/a])	ICSR
EU-EC- 10009753963	22/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Blood urine (n/a - Recovered/Resolved -), Glomerulonephritis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009754124	22/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Not Recovered/Not	COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10009754126	22/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Myalgia (3d - Recovered/Resolved -), Pruritus (n/a - Unknown -), Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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22/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
22/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
									Myalgia (n/a - Not Recovered/Not			
22/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Skin burning sensation (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
22/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
									Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Not			
22/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1 (DE) n/a])	Not reported	ICS
		Healthcare Professional	Non European Economic Area	available	Years	Specified			Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Ocular hyperaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash erythematous (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash erythematous (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICS
22/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
	22/08/2021 22/08/2021 22/08/2021 22/08/2021	22/08/2021 Spontaneous 22/08/2021 Spontaneous 22/08/2021 Spontaneous 22/08/2021 Spontaneous 22/08/2021 Spontaneous	22/08/2021 Spontaneous Healthcare Professional 22/08/2021 Spontaneous Healthcare Professional 22/08/2021 Spontaneous Healthcare Professional 22/08/2021 Spontaneous Professional 22/08/2021 Spontaneous Healthcare Professional 22/08/2021 Spontaneous Professional 22/08/2021 Spontaneous Healthcare Professional 22/08/2021 Spontaneous Healthcare Professional	Healthcare Professional European Healthcare Pro	Healthcare Professional Economic Area Savallable	Healthcare Professional Area 22/08/2021 Spontaneous Non Healthcare Professional Area 22/08/2021 Spontaneous Non Healthcare Professional Area Not Healthcare Professional Area 22/08/2021 Spontaneous Non Healthcare Professional Area Not Healthcare Professional Area Not Area 22/08/2021 Spontaneous Non Healthcare Professional Area 22/08/2021 Spontaneous Non Healthcare Professional Area Not Healthcare Professional Area Not Area Not available Years Not Area Not Area Not Area Not Area Not Area 12-17 Available Years 12-17 Area 22/08/2021 Spontaneous Non Healthcare Professional Area 22/08/2021 Spontaneous Non Healthcare Professional Economic Area 22/08/2021 Spontaneous Non Healthcare Economic Area 22/08/2021 Spontaneous Non Healthcare Professional Economic Area 22/08/2021 Spontaneous Non Healthcare Economic Area	Healthcare Professional Area Specified	Healthcare Professional Area European Realthcare Professional Area Not Realthcare Professional Not Realthcare Professional Area Not Realthcare Professional Area Not Realthcare Professional Not Realthcare Professiona	Healthcare Professional Area Professional	Healthcare Economic Aveal Professional Economic Professional Profes	Sportaneous Sportaneous	Pearline Pearline

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										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10009754522	22/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSI
										Resolved -)			<u> </u>
EU-EC- 10009754540	22/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
FIL FC	22/00/2021	Constant	Non	F	NI-4	12.17	Note	E I	NI-	-)	COMMUNICATIV	National	Teer
EU-EC- 10009754548	22/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009754555	22/08/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSF</u>
			Professional	Area						Myalgia (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Nausea (0d - Recovered/Resolved -)			
EU-EC- 10009754620		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -),		[PARACETAMOL, ACETYLSALICYLIC ACID, CAFFEINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009754628	22/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nasopharyngitis (n/a		Not reported	ICSF

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										- Not Recovered/Not Resolved -)			
EU-EC- 10009751012	21/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009751701	21/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovered/Resolved With Sequelae -), Pyrexia (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10009752282	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10009752331	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Unknown -)			_
EU-EC- 10009752402	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (36h - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009752639	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site discomfort (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009752778	21/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Angina pectoris (6d - Recovered/Resolved - Other Medically Important Condition), Arthropathy (3d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (6d - Recovered/Resolved - Other Medically Important Condition), Headache (4d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (0d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (0d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Intramuscular])	OPATANOL [OLOPATADINE, OLOPATADINE, HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - 1[drp] - Ophthalmic]), [ADAPALENE, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - 1{DF} - Cutaneous]), [AZELASTINE HYDROCHLORIDE, FLUTICASONE PROPIONATE] (C - Seasonal allergy - n/a - [n/a - 1{DF} - Nasal]), [BETAMETHASONE, BETAMETHASONE, BETAMETHASONE VALERATE] (C - Eczema - n/a - [n/a - 1{DF} - Cutaneous])	ICSR
EU-EC-		Spontaneous		European	Not	12-17 Years	Not	Male	No	Arthralgia (n/a - Not	COMIRNATY	[FLUTICASONE	ICSR
10009752812	l	1	Healthcare	Economic	available	Years	Specified	I		Recovered/Not	[TOZINAMERAN] (S -	PROPIONATE] (C -	

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			Professional	Area						Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009752831	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Malaise (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009752834	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009752842	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Myalgia (1d - Recovered/Resolved -), Nasopharyngitis (n/a - Not Recovered/Not			
EU-EC- 10009752902	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009752906	21/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -), Hypotension (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009740150	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Swelling of eyelid (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSE
EU-EC- 10009740657	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE, BECLOMETASONE DIPROPIONATE] (C - Seasonal allergy - n/a - [n/a - n/a - n/a]), [LORATADINE] (C - Seasonal allergy - n/a - [48d - n/a - n/a])	ICSR
EU-EC- 10009741010	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dry throat (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
	20.400.4200					10.17				Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			1000
EU-EC- 10009741050	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	20/08/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition) Blood pressure	COMIRNATY	Not reported	ICSR
10009741714			Professional		available	Years	Specified			decreased (n/a -	[TOZINAMERAN] (S -		2500

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				Area						Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved -), Hypoaesthesia (n/a - Recovered/Resolved	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10009741881	20/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Urticaria (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009741906	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009742158	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (3d - Recovered/Resolved - Disabling), Heavy menstrual bleeding (3d - Recovered/Resolved - Disabling), Migraine (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009742622	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Disabling) Arthralgia (6d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009743033	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Eye disorder (n/a - Unknown -), Gait inability (n/a - Unknown - Other Medically Important Condition), Herpes zoster (n/a - Unknown -), Rash (n/a - Unknown -), Rash pustular (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Vertigo (n/a - Unknown -),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009743215		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009743953	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not			
										Recovered/Not Resolved -), Injection site			
										swelling (n/a - Not Recovered/Not Resolved -), Rash papular (n/a -			
										Not Recovered/Not Resolved -)			
EU-EC- 10009743971	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-), Malaise (n/a - Not	COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not	1{DF} - n/a])		
EU-EC- 10009743977	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Arthralgia (18h - Recovered/Resolved -), Myalgia (72h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Nausea (10min - Recovered/Resolved -), Syncope (1h - Recovered/Resolved			
EU-EC-	20/08/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	-) Staphylococcal	COMIRNATY	Not reported	ICSR
10009744131			Healthcare Professional	Economic	available	Years	Specified			impetigo (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S -		
EU-EC- 10009744682	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Urticaria (15min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [0d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009744970	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009745440	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										-), Headache (2d - Recovered/Resolved -),	ייייי (וויפן)		
										Hyperhidrosis (0d - Recovered/Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Nausea (n/a -			

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										Recovering/Resolving -),			
										Presyncope (0d - Recovered/Resolved -)			
U-EC- 0009745518	20/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lip swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BUSPIRONE, BUSPIRONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBAMAZEPINE, CARBAMAZEPINE (PH. EUR.)] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Lymph node pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CAFFEINE] (C - n/a -	
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		n/a - [n/a - n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - n/a - n/a - n/a])	
										Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
U-EC- 0009745573	20/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved - Other Medically Important Condition), Intermenstrual bleeding (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Oral contraception - n/a - [n/a - n/a - Oral])	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 1.0009745884	20/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Disabling), Cough (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Disabling),			
										Recovered/Not Resolved - Disabling),			
										Influenza like illness (n/a - Not Recovered/Not Resolved - Disabling),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Disabling),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Disabling),			
										Vaccination site swelling (n/a - Not Recovered/Not Resolved - Disabling)			
:U-EC- .0009746138	20/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (24h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Fatigue (48h - Recovered/Resolved -), Somnolence (48h - Recovered/Resolved			
EU-EC-	20/00/2024	Spontaneous	Non	Europa	Not	12-17	Adolescent	Fores!-	No	-)	COMIRNATY	Not roperted	TCCC
L0009746146	20,00,2021	Sportaneous			available	Years	, addiesterit	Cinale		Application site pain (24h -	[TOZINAMERAN] (S -	Not reported	ICSF

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			Professional	Area						Recovered/Resolved	n/a - n/a - [n/a - n/a - Intramuscular])		
:U-EC- .0009746406	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	IC
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Tonsillar hypertrophy (n/a - Not Recovered/Not Resolved -)			
I-EC- 009746626	20/08/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	INTUNIV [GUANFACINE] (C - Hypertension - n/a -	
				Area						Chills (n/a - Unknown -),	immunisation - Not applicable - [n/a - n/a - n/a])	[n/a - n/a - n/a]), [LISDEXAMFETAMINE	
										Headache (n/a - Unknown -),		DIMESYLATE] (C - Attention deficit hyperactivity disorder	
										Nasopharyngitis (n/a - Unknown -),		- n/a - [n/a - n/a - n/a]),	
										Nightmare (n/a - Unknown -), Pyrexia (n/a -		[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma	
										Unknown - Other Medically Important Condition)		- n/a - [n/a - n/a - n/a])	
-EC- 009746773	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (10min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	
										-), Seizure (10min -	applicable - [n/a - n/a - n/a])		
										Recovered/Resolved - Other Medically Important Condition)			
I-EC- 009746853	20/08/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	маіе	No	Dyspnoea (1.5h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	
										Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	applicable - [n/a - 1{DF} - n/a])		
										Troponin I increased (3d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
J-EC- 009746922	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	
										Hospitalisation), Ascites (n/a - Unknown -	- Intramuscular])		
										Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Enterocolitis (n/a - Unknown - Caused/Prolonged			
										Hospitalisation, Other Medically Important Condition),			
										Condition),			
										Gastrointestinal inflammation (n/a - Unknown - Caused/Prolonged			
										Gastrointestinal inflammation (n/a - Unknown -			

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										Intussusception (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown -), Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10009746986	20/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adult	Female	No	Hospitalisation) Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009747094	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009747170	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009747182	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Influenza like illness (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	[DESOGESTREL] (C - n/a - n/a -)	ICSR
EU-EC- 10009747201	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009747324	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Disseminated intravascular coagulation (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Pulmonary haemorrhage (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (23h - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (23h -			
EU-EC-	20/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation) Arthralgia (n/a -	COMIRNATY	Not reported	ICSR
10009747628	20,00,2021	Sportraneous	Healthcare Professional	Economic	available	Years	Adolescent	Terriale	NV.		[TOZINAMFRAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	not reported	<u>ICSK</u>

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EU-EC- 10009747746	20/08/2021	Spontaneous	Healthcare Professional	European Economic	Not	12-17 Years	Not Specified	Female	No	-), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Migraine (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Not Recovered/Not Resolved -) Facial paresis (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						-), Nervous system disorder (n/a - Recovering/Resolving -), Peripheral nerve paresis (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009747975	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009747977	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009748017	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009748027		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009748105		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Disease recurrence (n/a - (n/a - Cother Medically Important Condition), Generalised tonic-clonic seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009748396	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009748407	20/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (n/a - Recovered/Resolved -), Pharyngeal swelling (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Recovered/Resolved -), Swollen tongue (n/a - Recovered/Resolved -), Tremor (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED O.A.C. [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

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EU-EC- 10009748462	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (0d - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition), Pulse abnormal (0d - Recovered/Resolved - Other Medically Important Condition), Pulse abnormal (0d - Recovered/Resolved - Other Medically Important Condition), Shock (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- 10009748565	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Syncope (8min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [0d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009748905	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009748981	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Interchange of vaccine products (1d - Recovered/Resolved -), Product administered to patient of inappropriate age (n/a - Recovered/Resolved -), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Unknown]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX- 024414)] (S - COVID- 19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009749944	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009750206	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009750247	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -), Vaccination site inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009750270		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009750299	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	ICSR

											withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10009750821	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bone pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Costochondritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrooesophageal reflux disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pulmonary pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMITRIPTYLINE, AMITRIPTYLINE HYDROCHLORIDE] (C - Migraine - n/a - [n/a - 25mg - Oral]), [MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - Oral]), [PREDNISONE] (C - Infection, Sinusitis - n/a - [5d - n/a - Oral]), [SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a - n/a])	ICSR
EU-EC- 10009725369	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Vaginal haemorrhage (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009725371		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Hypoacusis (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Muscle spasms (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Tremor (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009727377	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Ecchymosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Photophobia (n/a - Recovering/Resolving)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR

EU-EC-	19/08/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	Yes		TOZINAMERAN	Not reported	ICS
EU-EC- 10009728152	19/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Hospitalisation) Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Other Medically Important Condition), Lymph node pain (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
										Nasal congestion (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically			
										Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Somnolence (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009728829	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Balanoposthitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10009728871	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	<u>ICSF</u>
EU-EC- 10009728882	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eye swelling (n/a - Recovering/Resolving -), Lip swelling (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Pruritus (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)			
EU-EC- 10009729089	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cardiac disorder (n/a - Recovering/Resolving -), Exercise tolerance decreased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10009729187	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10009729192	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF

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										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009729701	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Auditory disorder			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Basilar migraine (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Deafness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Sensorimotor disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Throat tightness (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Tinnitus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Visual impairment			
										(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009729872	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -), Skin disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Not Recovered/Not Resolved -)	- n/a])		
EU-EC- 10009729998	19/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (4h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Myalgia (n/a - Recovering/Resolving -),	applicable - [n/a -		
										Rash pruritic (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009730420	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009730554	19/08/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
			Professional							Recovered/Resolved - Caused/Prolonged Hospitalisation),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Appendicitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Influenza like illness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009730610	19/08/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Economic Area	2.3.0010	. 50.5	2,5000			- Other Medically Important	COVID-19 immunisation - Not		

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										Condition), Disease recurrence (n/a - Recovered/Resolved - Other Medically	applicable - [1d - n/a - n/a])		
										Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10009730647	19/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Peroneal nerve palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009730697	19/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC- 10009731038	19/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Medically Important Condition) Bacille Calmette- Guerin scar reactivation (n/a - Not Recovered/Not Resolved -)	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL -	Not reported	ICSF
EU-EC- 10009731276	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Extrasystoles (n/a - Unknown - Caused/Prolonged	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSF
EU-EC- 10009731280	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Anaphylactic reaction (5h - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Blood pressure increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009731321	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (0d - Recovered/Resolved - Disabling), Blindness (0d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Blood pressure decreased (0d - Recovered/Resolved - Disabling),			
										Cyanosis (0d - Recovered/Resolved - Disabling),			
										Eye movement disorder (0d - Recovered/Resolved - Disabling),			
										Fatigue (0d - Recovered/Resolved - Disabling), Headache (0d -			
										Recovered/Resolved - Disabling),			
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										Malaise (0d - Recovered/Resolved - Disabling),			
										Movement disorder (0d - Recovered/Resolved - Disabling),			
										Myalgia (0d - Recovered/Resolved - Disabling),			
										Pallor (0d - Recovered/Resolved - Disabling)			
EU-EC- 10009731472	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -),	COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Headache (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	[TETANUS VACCINES] (C - n/a - n/a - [n/a - n/a - n/a])	
										Nausea (n/a - Recovered/Resolved -),			
										Vision blurred (5h - Recovered/Resolved -)			
EU-EC- 10009731509	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Body temperature increased (1d - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Chills (1d - Recovered/Resolved -),			
										Dizziness (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Recovering/Resolving -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009731522	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Feeling hot (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
EU-EC-	10/09/2021	Spontaneous	Haalthcara	European	Not	12-17	Adolescent	Eomalo	No	Malaise (n/a - Not Recovered/Not Resolved -) Bradycardia (2h -	COMIRNATY	Not reported	ICSR
10009731773	13/00/2021	Sportaneous	Professional		available	Years	Adolescent	Temale	No	Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	<u>ICSIN</u>
										Pallor (2h - Recovered/Resolved - Other Medically Important Condition),	.3mL - Intramuscular])		
										Peripheral coldness (2d - Recovered/Resolved - Other Medically Important			
										Condition), Presyncope (2h - Recovered/Resolved - Other Medically			
EU-EC- 10009732058	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Malaise (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Nausea (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Rash (n/a - Recovering/Resolving -),			

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										Swelling (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving			
EU-EC- 10009732104	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -),	COVID-19	[AZELASTINE HYDROCHLORIDE, FLUTICASONE	ICSR
										Dry eye (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Myalgia (1d - Recovered/Resolved -),			
										Ocular hyperaemia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10009732176	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (2d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[CYPROTERONE ACETATE, ETHINYLESTRADIOL, DAPHNE] (C - n/a -	ICSR
										Diarrhoea (2d - Recovered/Resolved - Disabling),	applicable - [n/a - n/a - n/a])	Unknown - [n/a - n/a - n/a])	
										Headache (2d - Recovered/Resolved - Disabling),			
										Menstrual disorder (2d - Recovered/Resolved - Disabling),			
										Nausea (2d - Recovered/Resolved - Disabling)			
EU-EC- 10009732386	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Circulatory collapse (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dysmenorrhoea (n/a - Recovered/Resolved			
										Nausea (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10009732686	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Faeces discoloured (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Fatigue (n/a - Unknown - Other Medically Important Condition),	- n/a])		
										Pain in extremity (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009732917	19/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Not Recovered/Not Resolved -),	COVID-19 immunisation - Not	Not reported	ICSR
										Abdominal pain (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - n/a - Intramuscular])		
										Abdominal pain upper (n/a - Not Recovered/Not Resolved -),			
										Chest discomfort (n/a - Not Recovered/Not			
										Resolved -), Condition aggravated (n/a - Not Recovered/Not Resolved -),			
										Feeding disorder (n/a - Unknown -),			
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										Gastritis (n/a - Unknown -),			
										Middle insomnia (n/a - Unknown -),			
										Nausea (n/a - Unknown -),			
										Oesophagitis (n/a - Unknown -),			
										Pain (n/a - Not Recovered/Not Resolved -),			
										Reflux gastritis (n/a - Not Recovered/Not			
										Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vomiting (n/a - Unknown -)			
EU-EC- 10009732983	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009732984	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009732986	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009732994	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn	Not reported	ICSR
										Resolved -), Arthralgia (n/a - Not Recovered/Not Resolved -),	- [n/a - n/a - Intramuscular])		
										Headache (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009733099	19/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Cardiac flutter (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Condition), Chest discomfort	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										(n/a - Unknown -), Decreased appetite (n/a - Unknown -),			
										Fatigue (n/a -			
										Pain in extremity			
										(n/a - Unknown -), Somnolence (n/a -			
EU-EC- 10009733309	19/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown -) COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Fatigue (n/a - Unknown -),	- Intramuscular])		
										Myalgia (n/a - Unknown -),			
										Rhinorrhoea (n/a - Unknown -),			
										Vaccination failure (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10009733311	19/08/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Asthenia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Back pain (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Headache (n/a - Unknown -),			
										Pain in extremity (n/a - Unknown -),			
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										Seizure (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition)			
EU-EC- 10009733446	19/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -), Myalqia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE, BECLOMETASONE DIPROPIONATE] (C - Seasonal allergy - n/a - [n/a - n/a - n/a]),	ICSR
										Unknown - Other Medically Important Condition), Pyrexia (n/a - Not	7,23	[LORATADINE] (C - Seasonal allergy - n/a - [48d - n/a - n/a])	
EU-EC-	19/08/2021	Spontaneous	Non	European	Not	12-17	Child	Male	No	Recovered/Not Resolved - Other Medically Important Condition) Chills (n/a -	COMIRNATY	Not reported	ICSR
10009733720	13/00/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Crina	Male	NO		[TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSI
										-), Dizziness (n/a - Recovering/Resolving			
										Fatigue (n/a - Recovering/Resolving -),			
										Hyperhidrosis (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a -			
										Recovering/Resolving -), Vaccination site pain (n/a -			
EU-EC- 10009734354	19/08/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	Yes	Recovering/Resolving -) B-lymphocyte count decreased (n/a -	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Economic Area						Unknown -), Haemolysis (3wk - Recovered/Resolved - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10009734567	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10009734618	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009734716	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (39d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC- 10009734748	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	·		
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			

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EU-EC- 10009734839	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a -)	ICSR
EU-EC- 10009734865	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009734902	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Motor dysfunction (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009735066	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Vertigo (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009735082	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009735085	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Burn oesophageal (n/a - Recovered/Resolved -), Decreased appetite (n/a - Recovered/Resolved -), Haematemesis (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009735251	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009735306	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Chest pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009735409	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009735789	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (8h - Recovered/Resolved - Disabling), Headache (18h - Recovered/Resolved - Disabling), Pyrexia (18h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovered/Resolved - Disabling)			
EU-EC- 10009735910	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
										Paraesthesia oral (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pharyngeal swelling (n/a - Unknown - Caused/Prolonged Hospitalisation),			
EU-EC-	19/08/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Sensation of foreign body (n/a - Unknown - Caused/Prolonged Hospitalisation) Myocarditis (n/a -	COMIRNATY	Not reported	ICSR
10009736117	19/06/2021	Sportaneous	Professional		available	Years	Specified	Male	INO	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSK
EU-EC-	19/08/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	- Unknown]) TOZINAMERAN	Not reported	ICSR
10009736119	13,000,2021	Spontaneous	Healthcare Professional	European	available	Years	Specified	lac		Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	not reported	10011
										Heart rate increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10009736246	19/08/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Haematoma (n/a - Not Recovered/Not Resolved -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSE
EU-EC- 10009736258	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown -) Arthralgia (n/a - Recovering/Resolving -),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Chills (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Cough (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not			
										Recovered/Not Resolved -), Malaise (n/a - Not			
										Recovered/Not Resolved -), Myalgia (n/a -			
										Recovering/Resolving -), Oropharyngeal pain			
										(n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -), Rhinorrhoea (n/a -			
EU-EC-	19/08/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Not Recovered/Not Resolved -) Seizure (n/a -	TOZINAMERAN	SERTRALINE,	ICSR
10009736623	, ==,=521	,	Healthcare Professional		available	Years	Specified			Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19	SERTRALINE HYDROCHLORIDE] (C	

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EU-EC- 10009737101	19/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Body temperature increased (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSI
										Myalgia (2d - Recovered/Resolved -)			
EU-EC- 10009738381	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICS
EU-EC- 10009738388	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICS
EU-EC- 10009738605	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 100097138736		Spontaneous	Professional Non Healthcare	European Economic	Not available	12-17 Years	Adolescent Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Respiratory failure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) Headache (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S -	[DESOGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a]) Not reported	ICSF
			Professional	Area						-), Injection site haematoma (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009714695	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Face oedema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS

Mail	0.11.2022 1	∠. 44							run Line	LISUN	g Report			
	10009716395			Professional	Economic	available	Years				clonic seizure (n/a - Unknown - Other Medically Important Condition), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10009717336 18/08/2021 Spontaneous Non Healthcare Professional		18/08/2021	Spontaneous	Healthcare	Economic				Male	No	Blood creatine phosphokinase increased (n/a - Recovering/Resolving -), C-reactive protein increased (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Neutrophilia (n/a - Recovering/Resolving -), Neutrophilia (n/a - Recovering/Resolving -), Troponin increased (n/a - Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
Professional Professional Professional Professional Economic Area Area Professional Professio	10009717336			Healthcare Professional	Economic Area	available	Years	Specified			Malaise (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Peripheral swelling (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pruritus (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Skin disorder (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Skin disorder (9d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ETHINYLESTRADIOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [IBUPROFEN, IBUPROFEN ARGININE] (C - n/a - Unknown - [n/a - n/a - n/a])	
EU-EC- 18/08/2021 Spontaneous Healthcare Non Not 12-17 Not Female No Erythema nodosum TOZINAMERAN [DOXYCYCLINE, ICSR		18/08/2021	Spontaneous		Economic				Male	No	Rash macular (n/a - Not Recovered/Not Resolved -), Rash pruritic (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	CETIRIZINE DIHYDROCHLORIDE]	ICSR
		18/08/2021	Spontaneous						Female	No	Resolved -) Erythema nodosum	TOZINAMERAN		ICSR

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				Economic Area						Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009718586	18/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adult	Female	No	Fatigue (4d - Recovered/Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Myalgia (n/a - Recovering/Resolving			
EU-EC- 10009718645	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (2d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
										Recovered/Resolved			
EU-EC- 10009718646	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
										Recovered/Not Resolved -),			
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving			
										Palpitations (n/a - Not Recovered/Not			
EU-EC- 10009718833	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Presyncope (10min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICS
EU-EC- 10009719429	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10009719446	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
EU-EC- 10009719493	18/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Anal incontinence (30s -	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
10003713.130			Professional	Area		19415	Specimou			Recovered/Resolved -),	COVID-19 immunisation - Not applicable - [n/a -		
										Arthralgia (n/a - Recovering/Resolving -),	1{DF} - n/a])		
										Chills (1h - Recovered/Resolved -),			
										Fatigue (n/a - Recovering/Resolving -),			
										Injection site pain (n/a - Recovering/Resolving			
										-), Malaise (12h -			
					1					Recovered/Resolved			

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										Myalgia (n/a - Recovering/Resolving -),			
										Nausea (7h - Recovered/Resolved -),			
										Syncope (30s - Recovered/Resolved -)			
EU-EC- 10009721213	18/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Malaise (n/a - Recovering/Resolving -),	applicable - [n/a -		
										Myalgia (n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Syncope (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10009721220	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Injection site erythema (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a])		
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site swelling (n/a - Not Recovered/Not Resolved -),			
										Injection site warmth (n/a - Not Recovered/Not Resolved -),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009721255	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009721272	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash pruritic (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009721688	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009721689	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR

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										Sinusitis (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009721690	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain upper (2wk - Recovering/Resolving -), Diarrhoea (2wk - Recovering/Resolving	immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
										-), Nausea (2wk - Recovering/Resolving	Tricumuscular j)		
										-), Vomiting (2wk - Recovering/Resolving			
EU-EC- 10009721691	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Intermenstrual bleeding (2wk - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
EU-EC- 10009721709	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009721806	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Malaise (1d - Recovered/Resolved -), Vision blurred (1d - Recovered/Resolved			
EU-EC- 10009721958	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009722008	18/08/2021	Spontaneous		1.	Not available	12-17 Years	Adult	Male	No	Injected limb mobility decreased (n/a - Recovered/Resolved -), Oedema (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009722611	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Abdominal pain (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[IBUPROFEN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Recovering/Resolving -),			
EU-EC- 10009723009	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -) Influenza like illness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	ICSF
										Multiple sclerosis relapse (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Visual field defect	withdrawn - [1d - 1{DF} - Intramuscular])		
										(n/a -			

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										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009723041	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vulval ulceration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009723453	18/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (n/a - Unknown - Other Medically Important Condition), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009724337	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ear pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009724359	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (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- 10009724477	18/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Unknown -), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Myalgia (n/a - Unknown -), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			
EU-EC-	18/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Fomalo	No	Condition), Pyrexia (n/a - Unknown -) Lymphadenopathy	COMIRNATY	COMIRNATY	ICSR
10009724609	10/00/2021	Sportaneous	Healthcare Professional	Economic		Years	Adolescent	remaie		(5d - Unknown -)	[TOZINAMERAN] (S -		ICSK
EU-EC- 10009724920	18/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10009725629	18/08/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Not Recovered/Not Resolved -) Blood immunoglobulin E (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
			Professional	Alea						Recovered/Not Resolved -), Neutropenia (n/a - Not Recovered/Not Resolved -)	[n/a - 2{DF} - n/a])		
EU-EC- 10009725713	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Generalised tonic- clonic seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009725745	18/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disturbance in attention (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

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EU-EC- 10009725753	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral])	ICSF
EU-EC- 10009725782	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Rash pruritic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009726068	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10009726076	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10009726080	18/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSF
EU-EC-	18/08/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Recovered/Resolved - Other Medically Important Condition) Myocarditis (n/a -	COMIRNATY	Not reported	ICSF
10009726114			Professional	Economic Area	available	Years				Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR])		
EU-EC- 10009700308	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC-	17/00/2021	Caratanas	Nam	F	Net	12.17	Nat	Mala	Na	Recovering/Resolving -)	COMIDNIATY	Natura	Tech
10009700693	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10009701930	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Injection site haematoma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009702029	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (n/a - Recovering/Resolving -), Asthenia (n/a - Recovering/Resolving -), Glossitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -), Headache (n/a - Recovering/Resolving -),			
										Oral herpes (n/a - Recovering/Resolving -)			
EU-EC- 10009703319	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Back pain (n/a - Not Recovered/Not Resolved -), Pain in extremity	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										(n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009703428	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009704029	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (0d - Recovered/Resolved -)	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR	Not reported	ICSR

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											DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])		
EU-EC- L0009704264	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009704603	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (2h - Recovered/Resolved -), Disturbance in	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
										attention (n/a - Recovering/Resolving -), Fatigue (n/a -	1{DF} - n/a])		
										Recovering/Resolving -), Feeling drunk (1h - Recovered/Resolved			
										-), Malaise (n/a - Recovering/Resolving -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (3h - Recovered/Resolved -)			
EU-EC- 10009704781	17/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (3d - Recovered/Resolved -),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	Not reported	ICS
										Oropharyngeal pain (3d - Recovered/Resolved -),	CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not		
										Pain in extremity (3d - Recovered/Resolved -),	applicable - [n/a - .3mL - Intramuscular])		
										Vaccination site oedema (3d - Recovered/Resolved -),			
										Vaccination site pain (3d - Recovered/Resolved -)			
EU-EC- 10009705018	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blood creatine phosphokinase MB increased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICS
										Blood creatine phosphokinase increased (n/a - Recovered/Resolved -),	Intramuscular])		
										Bundle branch block right (n/a - Recovered/Resolved -),			
										Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Joint effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovered/Resolved -),			
										Pain in extremity (n/a - Not			

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EU-EC- 10009705056	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Syncope (0d - Recovered/Resolved -)	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL -	Not reported	ICSF
EU-EC- 10009705133	17/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Body temperature increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Recovered/Not Recovered/Not Resolved - Other Medically Important Condition), Drug ineffective (n/a	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition), Suspected COVID-19			
EU-EC-	17/00/2021		New	Non	Not	12-17	Not	Male	N	(n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Asthenia (n/a - Not	TOTNAMEDAN	National	100
10009705956	17/08/2021	Spontaneous	Healthcare Professional	European	available	Years	Specified	Male	No	Recovered/Not Resolved -), Hallucination (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not			
										Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -),			
FILEC	17/02/5					12				Vital functions abnormal (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009706103	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (0d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]),	Not reported	ICSF

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Display											Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),	Infection - Not applicable - [n/a - n/a		
17/98/2021 Southanness Rom Perfections Property Company Prop											Recovering/Resolving -), Nausea (n/a - Not Recovered/Not			
Protestional Analysis		17/08/2021	Spontaneous					Adolescent	Female	No	Anaphylactic shock		Not reported	ICSR
EL-EC 17/08/2022 Sportlameous Healthcare Description Descrip	10009706345					available	Years				Recovered/Resolved - Caused/Prolonged	Immunisation - n/a -		
BUEC 17/08/2021 Spontaneous Healthcare European Most 12-17 Adolescent Mode No. Recovered/Resolving Concentration Con											(n/a - Recovered/Resolved - Caused/Prolonged			
											Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC 17/08/2021 Spontaneous Healthcare European Not		17/08/2021	Spontaneous		Economic			Adolescent	Male	No	diathesis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 17/08/2021 Spontaneous Healthcare European Not Not reported ICSR											thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged	Intramuscular])		
EU-EC- 17/08/2021 Spontaneous Healthcare European Professional Area Not 12-17 Adolescent Male Not Presyncept (EU-EC- 10009706905 Not Professional Area Not 12-17 Not											Recovering/Resolving - Caused/Prolonged			
TOZIMAMERAN (S - COVID-19 prophylaxis Cov											(n/a - Unknown - Caused/Prolonged Hospitalisation)			
Healthcare Economic Professional		17/08/2021	Spontaneous		Economic			Adolescent	Male	No	Recovered/Resolved - Other Medically	[TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a 3mL -	Not reported	ICSR
EU-EC- 10009706906 EU-EC- 10009706906 EU-EC- 100097070906 IVOS Spontaneous Healthcare Professional European Not 12-17 Not Specified Female No Not Not Specified Female No Not Not Specified Female No Not Not Specified Specified		17/08/2021	Spontaneous	Healthcare	Economic				Male	No	(6h - Recovered/Resolved -), Malaise (2h - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 1009705906 17/08/2021 Spontaneous Healthcare Professional Carea											Recovered/Resolved -),			
Healthcare Professional Profe											Recovered/Resolved			
EU-EC- 17/08/2021 Spontaneous Healthcare Professional Recovering/Resolving - Caused/Prolonged Hospitalisation), Pulmonary embolism (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Other Medically Important Condition) EU-EC- 17/08/2021 Spontaneous Non European Not 12-17 Not Female No Nausea (0d - COMIRNATY Not reported ICSR		17/08/2021	Spontaneous	Healthcare	Economic				Female	No	Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC- 1009707292											(3h - Recovered/Resolved			
Deep vein thrombosis (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pulmonary embolism (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation) - Caused/Prolonged Hospitalisation, Other Medically Important Condition) EU-EC- 17/08/2021 Spontaneous Non European Not 12-17 Not Female No Nausea (0d - COMIRNATY Not reported ICSR		17/08/2021	Spontaneous		Economic				Female	No	Coagulopathy (3d - Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not	ETHINYLESTRADIOL] (C - n/a - Unknown -	ICSR
Caused/Prolonged Recovering/Resolving Caused/Prolonged Hospitalisation, Other Medically Important Condition Commensation Commen											thrombosis (3d - Recovering/Resolving - Caused/Prolonged	- n/a])		
EU-EC- 17/08/2021 Spontaneous Non European Not 12-17 Not Female No Nausea (0d - COMIRNATY Not reported ICSR											(3d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically			
		17/08/2021	Spontaneous						Female	No	Nausea (0d -		Not reported	ICSR

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			Professional	Area						- Disabling), Vomiting (0d - Recovered/Resolved - Disabling)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009707586	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved -),			
										Headache (1d - Recovered/Resolved -),			
										Injection site reaction (1d - Recovered/Resolved -),			
										Malaise (1d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009707622	17/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Face oedema (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10009707879	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ocular icterus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009707963	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	17/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Paraesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY	Not reported	ICSR
10009708270	1770672021	Spontaneous	Healthcare Professional	Economic	available	Years	Adolescent	Temale		reaction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S -	Not reported	ICSK
										Meningism (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a - Recovered/Resolved			
										- Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10009708353	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009708378	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR

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	EU-EC- 10009708612		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiac discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved - Oaused/Prolonged Hospitalisation), Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) Lymph node pain (n/a - Not Recovered/Not Resolved -), Lymphalenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											(n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not			
	FU FC	17/00/2021	Cnantanaous	Lionithanus	Non	Not	12.17	Not	Malo	No	Resolved -)	COMIDNIATY	Not reported	TCCD
	EU-EC- 10009708628	17/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Dysphoria (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition)			
		17/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Headache (n/a - Not	COMIRNATY	Not reported	ICSR
	10009708868			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
											Myalgia (n/a - Recovering/Resolving -),			
											Pyrexia (n/a - Not Recovered/Not Resolved -)			
	EU-EC-	17/08/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Fatigue (0d -	COMIRNATY	Not reported	ICSR

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10009708890			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Purpura (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009708912	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Tremor (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009709330	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC- 10009709825	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009709827	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Vision blurred (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009709873	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved -), Influenza like illness (4d - Recovered/Resolved -), Menstruation delayed (n/a - Recovered/Resolved -), Vaccination site pain (4d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009709884	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Diarrhoea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009709886	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site induration (7d - Recovered/Resolved With Sequelae -), Vaccination site photosensitivity reaction (7d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009709943	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009710121	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009710181	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angina pectoris (0d - Recovered/Resolved -), Pulmonary pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - n/a - n/a - n/a - n/a - n/a]), [FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009710240	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site coldness (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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EU-EC- 10009710246	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSF</u>
										Dyspnoea (n/a - Recovering/Resolving -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Injection site inflammation (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site warmth (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009710339	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (30s - Unknown -), Head injury (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Unknown -), Loss of consciousness (30s -	applicable - [n/a - n/a - n/a])		
EU-EC-	17/08/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Unknown -) Malaise (1d -	COMIRNATY	Not reported	ICSF
10009710502	,,		Professional		available	Years					[TOZINAMERAN] (S - COVID-19		
EU-EC- 10009710509	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
EU-EC- 10009710569	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Atrioventricular block complete (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
EU-EC- 10009710617	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pneumothorax (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009710747	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (16s - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Vision blurred (5min - Recovered/Resolved			
EU-EC- 10009711021	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
										Fatigue (n/a - Recovering/Resolving -),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Recovering/Resolving			

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										-), Oropharyngeal pain (n/a - Recovering/Resolving -)			
EU-EC- 10009711135	17/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fibrin D dimer increased (n/a - Recovering/Resolving -), Inflammation (n/a - Recovering/Resolving -), Painful respiration (8d - Recovered/Resolved - Disabling), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Pulmonary fibrosis (n/a - Unknown - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Disabling), Vaccination site pain (1d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ALPHA-TOCOPHEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCONEXENT] (C - n/a - n/a - n/a - [n/a - n/a - n/a]), [FISH OIL] (C - n/a - n/a - n/a]), [GABAPENTIN] (C - Anxiety - n/a - [n/a - 1/a - 25mg - Oral]), [GAMMA-AMINOBUTYRIC ACID] (C - Anxiety - n/a - [n/a - n/a - n/a]), [ICOSAPENT] (C - n/a - n/a - n/a]), [L-THEANINE] (C - Anxiety - n/a - [n/a - 1/a - 1/a]), [L-THEANINE] (C - Anxiety - n/a - [n/a - 1/a]), [MELISSA OFFICINALIS LEAF] (C - n/a - n/a]), [MELISSA] (C - Anxiety - n/a - [n/a - 1/a]), [MELISSA] (C - n/a - n/a]), [VITAMINS NOS] (C - n/a - n/a - n/a]), [VITAMINS NOS] (C - n/a - n/a - n/a]), [WITHANIA SOMNIFERA ROOT] (C - Anxiety - n/a - [n/a - 1/a]), [WITHANIA SOMNIFERA ROOT] (C - Anxiety - n/a - [n/a - 1/a]), [WITHANIA SOMNIFERA ROOT] (C - Anxiety - n/a - [n/a - 1/a]),	ICSR
EU-EC- 10009711251	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaginal haemorrhage (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009711496	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Cough (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vertigo (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009711756	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hyperpyrexia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	BASIS VOOR SUSPENSIE (FAGRON) / BASIS VOOR SUSPENSIE FAGRON [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), DESLORATADINE 5 MG - ORODISPERSIBLE TABLET (C - n/a - n/a - [n/a - n/a]), NOVOMIX 30 PENFILL 100 U/ML SUSPENSION FOR INJECTION [INSULIN ASPART, INSULIN ASPART, INSULIN ASPART PROTAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE	ICSR

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												DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[COLISTIMETHATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[PANCREAS POWDER, PANCREATIN] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[URSODEOXYCHOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009712174	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Injection site inflammation (n/a - Not Recovered/Not			
										Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site warmth (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Unknown -),			
EU-EC-	17/08/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Nausea (n/a - Not Recovered/Not Resolved -) Epistaxis (0d -	COMIRNATY	Not reported	ICSR
10009712310	17/08/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Specified	Temale	NO	Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSK</u>
EU-EC- 10009712541	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10009712633	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Recovering/Resolving -), Vomiting (0d -	[n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
EU-EC-	17/08/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Resolved -) Headache (n/a -	1{DF} - n/a])	Not reported	ICSR
10009712644	1770072021	Spontaneous		Economic	available	Years	Specified	remale	NO	Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSIN
										Resolved -), Nausea (1d - Recovered/Resolved -),			
										Rhinorrhoea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009712769	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dry throat (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (1d - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (1d - Recovered/Resolved -),			
										Myalgia (3d - Recovered/Resolved -),			
										Oropharyngeal discomfort (0d - Recovered/Resolved -),			
										Rash (0d - Recovered/Resolved -)			
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EU-EC- 10009712919	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009712926	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving		[CLINDAMYCIN, ANHYDROUS BENZOYL PEROXIDE, CLINDAMYCIN, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC- 10009712933	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	[CHLORAMPHENICOL] (C - Eye infection - n/a - [n/a - n/a - Ophthalmic])	ICSR
EU-EC- 10009712937	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Recovering/Resolving -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009712938	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009712939	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - Contraception - Dose not changed - [n/a - 1{DF} - Oral])	Not reported	ICSR
EU-EC- 10009712943	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Headache (2d - Recovered/Resolved -), Tenderness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009712950	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site paraesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009712963	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Rash (4d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
EU-EC- 10009712976	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

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EU-EC- 10009712984	17/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Jaundice (n/a - Unknown -			
	17/00/0001					10.15				Caused/Prolonged Hospitalisation)			
EU-EC- 10009712996	17/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10009712999	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seasonal allergy (3d - Recovered/Resolved -), Urticaria (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009713002	17/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	-) Myalgia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10009/13002			Professional	Area	available	rears				-), Nausea (n/a - Recovering/Resolving -),	COVID-19 immunisation - Dose not changed - [n/a -		
										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10009713003	17/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
										Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not	1{DF} - n/a])		
EU EC	17/00/2021	Caratana	N	F	Net	12.17	A d - 1	F1-	NI-	Recovered/Not Resolved -)	COMIDNIATY	Natura	Teen
EU-EC- 10009713015	17/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Rhinorrhoea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Vaccination site pain (n/a - Recovering/Resolving			
EU-EC- 10009713017	17/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009713023	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal tenderness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
										Chest discomfort (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a])		
										Dyspnoea (n/a - Not Recovered/Not Resolved -), Palpitations (n/a -			
										Not Recovered/Not Resolved -), Vaccination site pain			
		eu/analytic		_						(n/a - Not			54/6

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										Recovered/Not Resolved -), Vaccination site			
EU-EC-	17/08/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	swelling (n/a - Not Recovered/Not Resolved -) Asthenia (n/a -	COMIRNATY	Not reported	ICSR
10009713048	17/00/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	Male	INO	Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - Not applicable - [n/a -	Not reported	<u>ICSI</u>
										Decreased appetite (n/a - Recovered/Resolved -),	.3mL - Intramuscular])		
										Eye pain (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10009713079	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009713080	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10009713084	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (1d - Recovered/Resolved -)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009713100	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),	- Intramuscular])		
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Insomnia (n/a - Unknown - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009713113	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	<u>ICSR</u>
EU-EC- 10009713131	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10009713135	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1d - Recovered/Resolved -)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1/DE) Unknown])	Not reported	ICSR
EU-EC- 10009713138	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved -)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009713140	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Haematuria (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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EU-EC- 10009713696	17/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -), Decreased appetite (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Somnolence (n/a - Recovered/Resolved - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009713790	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Dyspnoea (10min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009714176	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash pruritic (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009714218	17/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovered/Resolved -), Malaise (0d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009714235	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Syncope (1min - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009690613	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009690902	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disease recurrence (n/a - Unknown - Other Medically Important Condition), Epilepsy (n/a - Unknown - Other Medically Important Condition), Seizure (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- 10009690948	16/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Tonic convulsion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	SILDENAFIL CITRATE [SILDENAFIL CITRATE] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009691468	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paresis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoacusis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nodule (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [Id - n/a - Intramuscular])	Not reported	ICSR

EU-EC- 10009691498	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10009693011	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FLUTICASONE FUROATE] (C - Seasonal allergy - Not applicable - [n/a - n/a - n/a]),	ICS
EU-EC- 10009693024	16/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Croup infectious (4d - Recovered/Resolved - Other Medically Important Condition), Respiratory tract	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
										infection viral (4d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009693032	16/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Medically Important Condition), Maculopathy (n/a - Not Recovered/Not Resolved - Disabling),			
										Vision blurred (n/a - Not Recovered/Not Resolved - Disabling),			
EU-EC-	16/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Visual impairment (n/a - Not Recovered/Not Resolved - Disabling) Blindness (n/a -	TOZINAMEDANI	Not reported	ICS
10009693065	10/00/2021	spontaneous			available	Years	Specified	Мане	INO	Unknown - Other Medically Important Condition), Disorientation (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	100
										Unknown -), Fall (n/a - Unknown -),	,		
										Feeling abnormal (n/a - Unknown -), Headache (n/a - Unknown -),			
										Hypoacusis (n/a - Unknown -),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown -), Seizure (n/a -			
										Unknown - Other Medically Important Condition), Sleep disorder (n/a -			
										Unknown -), Tension (n/a - Unknown -),			
										Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition),			
										Vision blurred (n/a - Unknown -)			

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EU-EC- 10009693547	16/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Recovering/Resolving -), Eyelid oedema (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10009693861	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10009694093	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (2d - Unknown -), Body temperature increased (2d - Recovered/Resolved -), Insomnia (1d - Recovered/Resolved -), Syncope (2d - Unknown - Other Medically Important Condition), Vaccination site pain (2d - Recovered/Resolved -), Vomiting (2d - Unknown -), Yellow skin (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10009694615	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Unknown -) Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Rash (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10009695004	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Pericardial effusion (n/a - Recovered/Resolved - Caused/Polonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICS
EU-EC- 10009695049	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Asthma (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10009695225		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Recovered/Not Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009695395	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (3d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION	Not reported	ICSF

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											[TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL -		
EU-EC- 1.0009695552	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICS
										Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	.3mL - Intramuscular])		
:U-EC- .0009695785	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (1d - Recovering/Resolving -), Body temperature increased (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICS
										-), Diarrhoea (1d - Recovered/Resolved			
										-), Dizziness (n/a - Recovered/Resolved -),			
										Fatigue (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovered/Resolved -), Nausea (1d -			
										Recovered/Resolved -), Tinnitus (n/a - Recovered/Resolved			
										-), Vomiting (1d - Recovered/Resolved			
U-EC- 0009696799	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nasopharyngitis (n/a - Recovering/Resolving -)	immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
:U-EC- 0009696823	16/08/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICS
:U-EC- 0009696825	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICS
U-EC- 0009696826	16/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICS
										Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not			
EU-EC- .0009696860	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Lymphadenopathy (n/a - Recovering/Resolving -)	immunisation - Drug withdrawn - [1d - 1{DF} -	Not reported	ICS
EU-EC- .0009696920	16/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL -	Not reported	ICS
EU-EC- .0009696924	16/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (5d - Recovered/Resolved -), Influenza like illness (3d - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICS
		.eu/analytic		<u> </u>						Recovered/Resolved	Intramuscular])		59

										Rash (2d -			
										Recovered/Resolved			
EU-EC- 10009697070	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hyperhidrosis (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Vision blurred (n/a - Recovered/Resolved -)			
EU-EC- 10009697082	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Menstruation delayed (n/a - Recovering/Resolving -)			
EU-EC- 10009697087	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009697090	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009697205	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009697336	16/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009697337	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009697456	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovering/Resolving - Disabling), Headache (1d - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (1d - Recovering/Resolving - Disabling), Nausea (1d - Recovering/Resolving			
EU-EC- 10009697715	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Generalised tonic- clonic seizure (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	AZATHIOPRINE [AZATHIOPRINE] (C - Rasmussen encephalitis - n/a - [n/a - n/a - n/a]), LEVETIRACETAM [LEVETIRACETAM] (C	ICSR
										Psychogenic seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation,		- Epilepsy - n/a - [n/a - n/a - n/a]), [CLOBAZAM] (C - Epilepsy - n/a - [n/a - n/a - n/a]),	
										Other Medically Important Condition)		[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]),	
												[PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]),	
												[TOPIRAMATE] (C - Epilepsy - n/a - [n/a - n/a - n/a])	
EU-EC- 10009697740	16/08/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Economic Area						Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	1,741)		
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dysarthria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Photophobia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Slow response to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009697751		Spontaneous	Professional	Non European Economic Area	Not available	Years	Not Specified	Male	No	Myocarditis (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009697774	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009697835	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Diarrhoea (2d - Recovered/Resolved With Sequelae -),	immunisation - Not applicable - [1d - n/a - n/a])		
										Dizziness (n/a - Recovered/Resolved With Sequelae -),			
										Fatigue (2d - Recovered/Resolved With Sequelae -),			
										Fatigue (n/a - Recovered/Resolved With Sequelae -),			
										Gastrointestinal infection (n/a - Unknown -),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			

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EU-EC-	16/08/2021	Spontaneous		European	Not	12-17	Not	Female	No	Nausea (2d - Recovered/Resolved With Sequelae -) Aphthous ulcer (n/a -	COMIRNATY	Not reported	ICSR
10009698001			Healthcare Professional	Economic Area	available	Years	Specified			Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009698035	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Asthenia (n/a - Not Recovered/Not Resolved -), Myalgia (n/a -	applicable - [n/a - 1{DF} - n/a])		
										Recovering/Resolving -), Vertigo positional (2d			
										- Recovered/Resolved			
EU-EC- 10009698186	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	NOT AVAILABLE (C - n/a - n/a]) Not reported Not reported I ETHINYLESTRADIOL, LEVONORGESTREL, PLACEBO] (C - Contraception - n/a - [n/a - n/a - n/a]) Not reported Not reported	ICSR
										Fatigue (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	- n/a])		
										Headache (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Intermenstrual bleeding (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
	15/00/2001					10.17				Malaise (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMPAND.		1000
EU-EC- 10009698392	10/00/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pancreatitis acute (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009698452	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 1{DF} - Intramuscular])	LEVONORGESTREL, PLACEBO] (C - Contraception - n/a -	ICSR
										Pelvic pain (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Uterine inflammation (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)			
EU-EC- 10009698493	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009698615	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (1d - Recovered/Resolved - Other Medically Important Condition), Tachycardia (1d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009698625	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Fall (1d - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR

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										Condition), Influenza like illness (2d - Recovered/Resolved	[1d3mL - Intramuscular])		
										Joint dislocation (1d			
										Recovering/Resolving - Other Medically Important Condition),			
										Malaise (1d - Recovered/Resolved -),			
										Seizure (1d - Recovered/Resolved -)			
EU-EC- 10009698893	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009698898	16/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	-) Malaise (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	[RISPERIDONE] (C - n/a - n/a - [n/a - n/a -	ICSR
				Area			·			Resolved -), Nausea (n/a - Not Recovered/Not	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a])	
EU-EC- 10009698931	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
			FIOLESSIONAL	Alea						Fatigue (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a	
										Headache (n/a - Not Recovered/Not Resolved -),		- n/a])	
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009699561	16/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Arthropod bite (n/a - Unknown -), Peripheral swelling	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										(n/a - Recovered/Resolved -),	applicable - [n/a - n/a - n/a])	[LORATADINE] (C - Seasonal allergy - n/a - [n/a - n/a - n/a])	
										Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009700124	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cystitis noninfective (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700362	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	AVAMYS [FLUTICASONE FUROATE] (C -	ICSR
										Nasopharyngitis (n/a - Recovering/Resolving	immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Rhinorrhoea - n/a - [n/a - n/a - Nasal])	
										-), Oropharyngeal pain			
										(n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10009700366	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700369	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
										Pain in extremity (0d - Recovered/Resolved	immunisation - Unknown - [n/a - 1{DF} - n/a])		
EU-EC-	16/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	-) Oropharyngeal pain	COMIRNATY	OPATANOL COLORATA DIALE	ICSR
10009700374			Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Dose	[OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a	

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										Pyrexia (n/a - Not Recovered/Not Resolved -)	not changed - [n/a - 1{DF} - n/a])	- [n/a - n/a - Ophthalmic]), [AZELASTINE, AZELASTINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]), [CLOBETASOL PROPIONATE] (C - Eczema - n/a - [n/a -	
EU-EC- 10009700376	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	n/a - Cutaneous]) Not reported	ICSR
EU-EC- 10009700380	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Rash (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700384		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700386	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700388	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700390	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Influenza (5d - Recovered/Resolved -), Rash (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009700392	16/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Menstrual disorder (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700396		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Ageusia (12d - Recovered/Resolved -), Chest pain (0d - Recovered/Resolved -), Cough (n/a - Recovering/Resolving -), Headache (10d - Recovered/Resolved -), Nasopharyngitis (8d - Recovered/Resolved -), Oropharyngeal pain (10d - Recovered/Resolved -), Pyrexia (12d - Recovered/Resolved -), Pyrexia (12d - Recovered/Resolved -) Ear discomfort (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700397	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ear discomfort (n/a - Unknown -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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										-), Nausea (n/a - Recovering/Resolving -), Parosmia (n/a - Unknown -), Vomiting (n/a -			
EU-EC- 10009700401	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown -) Erythema (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Skin warm (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	[CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [FEXOFENADINE HYDROCHLORIDE] (C - Urticaria - n/a - [n/a - n/a - Oral]),	ICSR
										Recovered/Not Resolved -)		[FLUOCORTOLONE PIVALATE PH. EUR., ANHYDROUS LIDOCAINE HYDROCHLORIDE, FLUOCORTOLONE PIVALATE PH. EUR., LIDOCAINE HYDROCHLORIDE, FLUOCORTOLONE PIVALATE, ANHYDROUS LIDOCAINE HYDROCHLORIDE, FLUOCORTOLONE PIVALATE, LIDOCAINE HYDROCHLORIDE, FLUOCORTOLONE PIVALATE, LIDOCAINE HYDROCHLORIDE] (C - Anal fissure - n/a - [n/a - n/a - Rectal]),	
												[MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a - Oral])	
EU-EC- 10009700403	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Contusion (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose increased - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009700405	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700411	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eczema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	[CICLESONIDE] (C - Asthma prophylaxis - n/a - [n/a - n/a - Respiratory (inhalation)]), [HYDROCORTISONE	ICSR
												BUTYRATE] (C - n/a - n/a - [n/a - n/a - Cutaneous]),	
												[MOMETASONE FUROATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]),	
												[PIMECROLIMUS] (C - n/a - n/a - [n/a - n/a - Cutaneous]),	
												[TERBUTALINE SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	
EU-EC- 10009700416	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700418	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Unknown -), Rash (n/a - Unknown -), Swelling face (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

☆ ☆ ⊕ ③ Rows 12001 - 12500

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