## Line Listing Report Time run: 30/11/2022 11:22:32

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])	
EU-EC- 10010007412	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovered/Resolved - ), Body temperature increased (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL, ACETYLSALICYLIC ACID, CAFFEINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										- ), Chills (0d - Recovered/Resolved - ),			
										Fatigue (n/a - Recovering/Resolving - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										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 - Recovering/Resolving - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010007469	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Heavy menstrual bleeding (n/a - Recovered/Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
EU EC	15/00/2021	Constant	11	New	Note	12.17	Not	F1-	N	Menstrual disorder (n/a - Unknown - )	COMIDNIATY	Notes	100
EU-EC- 10010007713	15/09/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICS
EU-EC- 10010007758	15/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tachycardia (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10010007928	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (3d - Recovered/Resolved - ), Polymenorrhoea (8d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010007960	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 10010007985	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (34d - Recovered/Resolved - ), Chills (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Fatigue (24h - Recovered/Resolved - ),			

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										Headache (6h - Recovered/Resolved - ), Malaise (6h - Recovered/Resolved - ),			
										Menstrual disorder (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (6h - Recovered/Resolved -			
EU-EC- 10010007991	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - )			
EU-EC- 10010007998	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (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- 10010008142	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dry throat (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
										Unknown - Caused/Prolonged Hospitalisation),  Pyrexia (n/a - Unknown -			
EU EC	15/00/2021	Coopten	N	F	Not	12.17	Niet	FI-	NI-	Caused/Prolonged Hospitalisation)	COMIDMATI	Net verested	TOOD
EU-EC- 10010008712	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010008799	15/09/2021	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), Cold sweat (0d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										), Headache (0d - Recovered/Resolved -			
										), Presyncope (0d - Recovered/Resolved -			
EU-EC- 10010008809	15/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (1wk - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010008867	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	15/09/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Hospitalisation) Asthenia (n/a -	COMIRNATY	Not reported	ICSR

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2006/2003   2007/amenas   Healthorie   Control   Scoronic   Scor	10010008892			Professional		available	Years				Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Muscle twitching (10s - Recovered/Resolved - Other Medically	COVID-19 immunisation - Not applicable - [n/a - 1{DF} -		
13-00-000-000-000-000-000-000-000-000-00	EU-EC- 10010008906	15/09/2021	Spontaneous		Economic				Female	No	Pulmonary embolism (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC-   15/09/2021   Spontaneous   Healthcare   Economic   Area   Mode   European   Area   Mode   Economic   Area   Mode   Mo	EU-EC- 10010008936	15/09/2021	Spontaneous	Healthcare	European Economic				Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (5d - Recovered/Resolved - ), Heart rate increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lethargy (n/a - Unknown - ), Malaise (n/a - Unknown - ), Vein collapse (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	ETHINYLESTRADIOL, ETHINYLESTRADIOL PH. EUR., DESOGESTREL B.P.] (C - Menstruation irregular - n/a - [n/a -	ICSF
15/09/2021   Spontaneous   Non Healthcare Professional   Not Committee   Professional   Not Professional	EU-EC- 10010008957	15/09/2021	Spontaneous		European Economic				Female	No	Seizure (n/a - Recovered/Resolved - Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	(C - n/a - n/a - [n/a -	ICSF
ELPEC- 1010010075   Spontaneous   Non Heathcare   Heat	EU-EC- 10010009341	15/09/2021	Spontaneous	Healthcare	Economic			Adolescent	Female	No	Recovered/Resolved - Other Medically Important Condition), Hypertension (0d - Recovered/Resolved - ), Loss of consciousness (1min - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved - Other Medical Resolved - O	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSF
	EU-EC- 10010010075	15/09/2021	Spontaneous	Healthcare	Economic				Female	No	Asthenia (n/a - Unknown - ),  Blood pressure decreased (0d - Recovered/Resolved - ),  Catatonia (0d - Recovered/Resolved - ),  Cough (n/a - Not Recovered/Not Resolved - ),  Limb discomfort (n/a - Recovering/Resolving - ),  Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),  Mydriasis (0d - Recovered/Resolved - ),  Nausea (0d - Recovered/Resolved - ),  Pain in extremity (n/a - Unknown - ),  Rash (n/a - Unknown	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSF

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EU-EC- 10010010206	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - ), Presyncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010010400	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010010603	15/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aspartate aminotransferase increased (5d - Recovered/Resolved - ),  Blood creatine phosphokinase MB increased (5d - Recovered/Resolved - ),  Blood creatine phosphokinase increased (5d - Recovered/Resolved - ),  Chest pain (5d - Recovered/Resolved - ),  Chest pain (5d - Recovered/Resolved - ),  Electrocardiogram ST segment elevation (5d - Recovered/Resolved - Recov	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10010010607	15/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Other Medically Important Condition) Anaphylactic reaction (n/a - Recovering/Resolving - Life Threatening), Feeling abnormal (n/a - Recovering/Resolving - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Loss of consciousness (n/a - Recovering/Resolving - Life Threatening), Pain in extremity (n/a - Recovering/Resolving - Life Threatening), Rash (n/a - Recovering/Resolving - Life Threatening), Urticaria (n/a - Recovering/Resolving - Recovering/Resolving)			
EU-EC- 10010010628	15/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Life Threatening) Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010010895	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10010010972	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypersensitivity (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10010010983	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Chest pain (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Supraventricular tachycardia (1d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Subcutaneous])	Not reported	ICSI

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										Resolved - Other Medically Important Condition)			
EU-EC- 10010010995	15/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011045	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011075		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Specified	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010011087	15/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010011093	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010011149	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011186	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash maculo-papular (5d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011296	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011311	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011349	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved - ), Euphoric mood (1d - Recovered/Resolved - ), Flushing (n/a - Recovered/Resolved - ), Pustule (16d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [40d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011378	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (n/a - Recovering/Resolving - ), Inflammatory bowel disease (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011387	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	Yes	- ) Pruritus (n/a - Recovering/Resolving - ), Skin reaction (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [32d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011388	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Urticaria (11d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011396	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011415	15/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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				Area						Laryngeal discomfort (n/a - Unknown - )	COVID-19 immunisation - Not applicable - [1d - 1{DF} -		
EU-EC- 10010011435	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Myalgia (n/a - Recovered/Resolved - ),			
										Rhinitis (n/a - Recovered/Resolved - )			
EU-EC- 10010011439	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (14d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010011460	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Face oedema (4d - Not Recovered/Not Resolved - ), Rash (4d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011488	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palmar-plantar erythrodysaesthesia syndrome (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011489	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved - ), Menometrorrhagia (20d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]),	Not reported	ICSR
											[ETHINYLESTRADIOL, NORGESTIMATE] (S - Contraception - Drug withdrawn - [n/a - n/a - n/a])		
EU-EC- 10010011506	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011511	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Recovered/Resolved - ), Swollen tongue (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010011552	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - ), Hot flush (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Resolved - ),  Paraesthesia (n/a - Not Recovered/Not	<u>, , , , , , , , , , , , , , , , , , , </u>		
EU-EC- 10010011560	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Diabetes mellitus inadequate control (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Hypoglycaemia (n/a - Recovered/Resolved - )	1{DF} - Intramuscular])		
EU-EC- 10010011602	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (1d - Recovered/Resolved - ), Influenza like illness (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[QUETIAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										,		[TESTOSTERONE ENANTATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010011769	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved - ), Fatigue (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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										), Headache (2d - Recovered/Resolved - ),			
										Heavy menstrual bleeding (n/a - Recovering/Resolving - ),			
										Malaise (2d - Recovered/Resolved - ),			
										Menstrual disorder (n/a - Recovering/Resolving -),			
										Menstruation delayed (n/a - Recovering/Resolving -),			
										Myalgia (1d - Recovered/Resolved - )			
EU-EC- 10010011801	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Vulval ulceration (n/a - Not Recovered/Not Resolved - )	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010012710	15/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Blood pressure decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1,41)		
										Feeling abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Oxygen saturation decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010012839	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2wk - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSR
EU-EC- 10010012936	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - ),	Intramuscular])  COMIRNATY  [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Malaise (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10010012949	15/09/2021	Spontaneous		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
										Chills (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		

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										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 - )			
EU-EC- 10010013228	15/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010014359	15/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BUDESONIDE [BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma	ICSR
										Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),		- n/a - [n/a - n/a - n/a])	
										Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Myositis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Pyrexia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10010014632	15/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rhabdomyolysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010014636	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	15/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Local reaction (5d -	COMIRNATY	Not reported	ICSR

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10010014680			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])		
EU-EC- 10010014702	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Pruritus (6d - Recovered/Resolved - ), Urticaria (6d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010014714	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Erythema multiforme (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC-	15/00/2021	Spontaneous	Hoaltheare	European	Not	12-17	Not	Male	No	Vasculitis (2d - Recovered/Resolved - ) Deep vein thrombosis	COMIRNATY	Not reported	ICSF
10010014899	13/03/2021	Sportaneous	Professional		available	Years	Specified	Male	NO	(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	1031
EU-EC- 10010015159	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (7d - Unknown - ), Injection site pain (2d - Recovered/Resolved - ),		Not reported	ICSF
										Intermenstrual bleeding (3d - Recovered/Resolved -			
EU-EC- 10010015196	15/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	- n/a])		
EU-EC- 10010015649	15/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure systolic decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Electrocardiogram Q wave abnormal (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Electrocardiogram QRS complex prolonged (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Electrolyte imbalance (n/a - Recovered/Resolved - ),			
										Epilepsy (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Generalised tonic- clonic seizure (10s - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Ventricular fibrillation (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010015780	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL -	Not reported	ICSF
										Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a -	.3mL - Intramuscular])		
EU-EC-	15/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Unknown - Other Medically Important Condition) Eyelid oedema (3d -	COMIRNATY	Not reported	ICSR
10010015798 tns://dan.er	' '		Healthcare	Economic			Adolescent	Cinale	140		[TOZINAMERAN] (S -	Not reported	9/4

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			Professional	Area						Other Medically Important Condition), Musculoskeletal chest pain (3d - Recovered/Resolved - Other Medically Important Condition), Tinnitus (5d - Recovered/Resolved - Other Medically	COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		
										Important Condition)			
EU-EC- 10010015820	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [2d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010015825	15/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Myalgia (n/a - Recovering/Resolving - ),  Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10010015845	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10010015855	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010015859	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymph node pain (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (3d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Caused/Prolonged Hospitalisation), Syncope (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010015863	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC- 10010015931	15/09/2021	Spontaneous		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} - Intramuscular])	Not reported	ICSR
EU-EC- 10010015933	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sinus tachycardia (2d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC-	15/09/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	- Recovered/Resolved - Caused/Prolonged Hospitalisation) Facial paralysis (n/a -	COMIRNATY	Not reported	ICSR
10010015935				Economic Area	available	Years				Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])		
EU-EC- 10010015938		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	- n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - Attention deficit hyperactivity disorder - Dose not changed - [n/a - n/a - n/a])	ICSR
EU-EC- 10010015939	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010015977	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vulval ulceration (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010016188	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [39d - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010016202	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Purpura (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010016226	15/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010016320	15/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (0d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010016404	15/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Important Condition) Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - ),	[TOZINAMERAN] (S -	Not reported	ICSR
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010016432	15/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Rash papular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Swelling face (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010016569	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010016726	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - ) Herpes virus infection (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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										Recovered/Not Resolved - )	n/a - n/a - [n/a -		
EU-EC- 10010016769	15/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Photophobia (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other	1{DF} - n/a]) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009987334	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) Polymenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 10009987423	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenitis (n/a - Not Recovered/Not Resolved - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a5mL -	Not reported	ICSR
EU-EC- 10009987491	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009987500	14/09/2021	Spontaneous	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/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009988335	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009988460	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Diarrhoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009988797	14/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (4d - Recovered/Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009989040	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	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 Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009989678	14/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypotension (3d - Recovered/Resolved - Other Medically Important Condition), Pain (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

										Medically Important Condition)			
EU-EC- 10009989801	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Muscle strain (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10009990164		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009990353	14/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),  Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition),  Malaise (n/a - Recovered/Resolved - ),  Oropharyngeal pain (n/a - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10009990379	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009990384	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009990387	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009990954	14/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition)		Not reported	ICSR
EU-EC- 10009991029	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009991309	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - ), Malaise (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009991344	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alcohol use (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pancreatitis acute (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009991383	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009991648	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (6d - Recovered/Resolved - ), Headache (6d - Recovered/Resolved - ), Heavy menstrual bleeding (6d - Recovered/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])	ICSR

D.11.2022 1: EU-EC- 10009991741		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Polymenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009991753	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009991756	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Chills (n/a - Recovered/Resolved - ), Fatigue (n/a -			
										Recovered/Resolved - ), Headache (n/a - Recovered/Resolved -			
										), Pyrexia (n/a - Recovered/Resolved -			
EU-EC- 10009991835	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pneumothorax spontaneous (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10009992053	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10009992212		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10009992301	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
										Pericardial effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10009992422	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (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- 10009992510		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Menstrual disorder (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009992513		·		European Economic Area	Not available	12-17 Years	Adolescent		No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009992700	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009992702	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vertigo (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009992703	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oropharyngeal pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009992704		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009992928	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (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	ICSF
										Nausea (n/a - Not			

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										Recovered/Not Resolved - )			
EU-EC- 10009992933	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - ), Urticaria (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	NOT AVAILABLE (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
										Vomiting (n/a - Unknown - )	- n/a])		
EU-EC- 10009992953	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009992961	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Balance disorder (n/a - Recovered/Resolved - Other Medically		[CARBAMAZEPINE, CARBAMAZEPINE (PH. EUR.)] (C - Epilepsy - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
										Developmental delay (n/a - Recovered/Resolved - ),	[TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]),	
										Epilepsy (n/a - Recovered/Resolved - Other Medically Important Condition),		[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a])	
										Fatigue (n/a - Recovered/Resolved - ), Nasopharyngitis (n/a			
										- Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovered/Resolved - ),			
										Partial seizures (3d - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (4d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009993749	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Palpitations (0d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])	<u>ICSR</u>
EU-EC- 10009993869	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (1mo - Recovered/Resolved - ),	immunisation - Not applicable - [n/a -	Not reported	ICSR
										Polymenorrhoea (7d - Recovered/Resolved - )	1{DF} - n/a])		
EU-EC- 10009993941	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactoid reaction (3d - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Cardiovascular disorder (3d - Unknown - Other Medically Important Condition),	. 3		
										Chills (3d - Unknown - Other Medically Important Condition),			
										Erythema (3d - Unknown - Other Medically Important Condition),			
										Fatigue (3d - Unknown - Other Medically Important Condition),			
										Headache (3d - Unknown - Other Medically Important Condition),			
										Hypotension (3d - Unknown - Other Medically Important Condition),			

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										Pharyngeal swelling (3d - Unknown - Other Medically Important Condition),			
										Pyrexia (3d - Unknown - Other Medically Important Condition),			
										Tachycardia (3d - Unknown - Other Medically Important Condition)			
EU-EC- 10009994043	14/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	- n/a])		
										Pallor (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Presyncope (n/a - Unknown - )			
EU-EC- 10009994194	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- ),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S -	Not reported	ICSR
										Nausea (n/a - Unknown - ),	COVID-19 immunisation - Not applicable - [n/a - n/a		
	/ /									Vomiting (n/a - Unknown - )	- n/a])		
EU-EC- 10009994730	14/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])	ICSR
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),	- n/a])		
EU-EC-	14/09/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition) Chills (1d -	COMIRNATY	Not reported	ICSR
10009994855	14,05,2021	Spontaneous		Economic	available	Years	Specified	Hale		Recovered/Resolved - ), Dizziness (1d - Recovered/Resolved -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSIN
										), Fatigue (1d - Recovered/Resolved - ),			
										Malaise (1d - Recovered/Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
	11/02/0201			_		12.12				Pyrexia (1d - Recovered/Resolved - )			
EU-EC- 10009995063	14/09/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovering/Resolving - ), Malaise (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE	Not reported	ICSR
										Recovering/Resolving - ),	(NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S -		
										Nausea (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Vomiting (n/a -   Recovering/Resolving  - )			
EU-EC- 10009995214	14/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)	,		
EU-EC- 10009995335	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Not Recovered/Not Resolved - ),	COMIRNATY CONCENTRATE FOR DISPERSION FOR	Not reported	ICSR

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										Rash (n/a - Not Recovered/Not Resolved - )	INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009995375	14/09/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - ), Discouragement (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										- Recovering/Resolving	- Intramuscular])		
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Ear discomfort (n/a - Recovering/Resolving - ),			
										Hypersensitivity (n/a - Unknown - Other Medically Important Condition),			
										Laryngopharyngitis (n/a - Recovering/Resolving - ),			
										Pain (n/a - Recovering/Resolving - ),			
										Pharyngotonsillitis (n/a - Unknown - Other Medically Important Condition),			
										Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Suspected COVID-19 (n/a - Unknown - ),			
										Urticaria (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009995840	14/09/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Back pain (1d - Recovered/Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Gait inability (n/a - Not Recovered/Not Resolved - Disabling),	immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Neuropathy peripheral (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009995888	14/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a])	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	- n/a])		
EU-EC- 10009996279	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	ICSR

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EU-EC- 10009996335	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009996423	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009996467	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Psoriasis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009996502	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009996550	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (3d - Recovered/Resolved - ), 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- 10009996554	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Skin lesion (n/a - Not Recovered/Not Resolved - ), Testicular injury (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009996557	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009996612		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009996965	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Unknown - )	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009997288	14/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC- 10009997523	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009997568		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - ), Menstruation delayed (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009997828	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - ), Diarrhoea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	14/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Confusional state	TOZINAMERAN	Not reported	ICSR

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10009997893			Healthcare Professional	European Economic Area	available	Years	Specified			(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paranoia (n/a - Not Recovered/Not Resolved - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010000171	14/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation)  Amenorrhoea (1mo - Not Recovered/Not Resolved - ),  Myalgia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010000792	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [1d - n/a - Intramuscular])	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - Dose not changed - [n/a - n/a - n/a])	ICSR
EU-EC- 10010000793	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (3d - Recovered/Resolved - ), Pyrexia (3d - Recovered/Resolved - ), Vaccination site lymphadenopathy (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010000840	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010000898	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC- 10010001094	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diplopia (4d - Recovering/Resolving - Other Medically Important Condition), Headache (2d - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010001101	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Vaccination site inflammation (n/a - Not Recovered/Not Resolved - ), Vaccination site oedema (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - n/a])	[PARACETAMOL] (C - Pain - n/a - [2d - n/a - n/a])	ICSR
EU-EC- 10010001103	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site oedema (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010001104	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010001144	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010001145	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010001149	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Vomiting (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010001153	14/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site erythema (n/a - Recovered/Resolved - ), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - ),  Vaccination site pain (n/a -			
EU-EC-	14/00/2021	Cnontangous	Hoalthcaro	Europoan	Not	12-17	Adolescent	Eomalo	No	Recovered/Resolved - ) Cerebral	COMIDNATY	Not reported	ICCD
10010001154	14/09/2021	Spontaneous	Professional	European Economic Area	available	Years	Adolescent	remale	INO	Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown - More in ICSR])	Not reported	ICSR
EU-EC- 10010001156	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										Petechiae (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010001164	14/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema annulare (43d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[PREDNICARBATE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Topical])	ICSR
EU-EC- 10010001170	14/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010001879	14/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (4d - Recovered/Resolved - Other Medically Important Condition), Arthralgia (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
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010002811	14/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),	applicable - [1d - n/a - n/a])		
										Inflammation (n/a - Not Recovered/Not Resolved - ),			
ELL EC	12/00/202	Constitution	Has like	- Fare-	Not	12.4-	Net	Mel	NI-	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIDNATI	Net vor	Iccs
EU-EC- 10009974198	13/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (23d - Recovered/Resolved -	COMIRNATY  [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>

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				Area						Other Medically Important Condition), Hemiplegia (23d - Recovered/Resolved - Other Medically Important Condition)	COVID-19 prophylaxis - Not applicable - [n/a 3mL - Intramuscular])		
EU-EC- 10009974213	13/09/2021	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 - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009974219	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (11d - Recovered/Resolved - ), Dyspnoea (11d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10009974403	13/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Disabling), Blood creatine increased (n/a - Not Recovered/Not Resolved - Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	HUMIRA [ADALIMUMAB] (C - n/a - n/a - [n/a - n/a - n/a])	ICSI
										Burning sensation (n/a - Not Recovered/Not Resolved - Disabling),			
										Chest discomfort (n/a - Not Recovered/Not Resolved - Disabling), Chest pain (n/a - Not			
										Recovered/Not Resolved - Disabling), Dyspnoea (n/a - Not Recovered/Not			
										Resolved - Disabling), Eructation (n/a - Not Recovered/Not Resolved - Disabling),			
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling),			
										Gait inability (n/a - Not Recovered/Not Resolved - Disabling), Gastrooesophageal			
										reflux disease (n/a - Not Recovered/Not Resolved - Disabling),			
										Hyperacusis (n/a - Not Recovered/Not Resolved - Disabling), Hypertension (n/a -			
										Not Recovered/Not Resolved - Disabling), Inflammatory marker increased (n/a - Not			
										Recovered/Not Resolved - Disabling), Migraine (n/a - Not Recovered/Not			
										Resolved - Disabling), Oropharyngeal pain (n/a - Not Recovered/Not			
										Resolved - Disabling), Pain (n/a - Not Recovered/Not Resolved - Disabling),			
										Photophobia (n/a - Not Recovered/Not Resolved - Disabling),			
										Throat tightness (n/a - Not Recovered/Not Resolved - Disabling), Vomiting (n/a - Not			
EU-EC- 10009974441	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - Disabling) Fatigue (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[LEVOCETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a -	ICSI

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										Unknown - ),	applicable - [n/a - n/a - n/a])		
										Presyncope (n/a - Unknown - ),			
										Tinnitus (n/a - Unknown - ),			
										Vaccination site pain			
										(14h - Recovered/Resolved -			
										), Vision blurred (n/a -			
EU-EC-	12/00/2021	Cnantanagus	Non	Non	Not	12.17	Not	Mala	No	Unknown - )	TOZINAMEDAN	Not reported	TCCD
10009974469	13/09/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
				Area						Medically Important Condition),	immunisation - Not applicable - [1d - n/a		
										Nausea (n/a - Not	- n/a])		
										Recovered/Not Resolved - Other Medically Important			
EU-EC-	13/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Not	No	Condition)  Chest pain (n/a - Not	TOZINAMERAN	Not reported	ICSR
10009974474	15/05/2021	Sportarious	Healthcare Professional	European	available	Years	Specified	Specified		Recovered/Not Resolved - Other	[TOZINAMERAN] (S - COVID-19	The reported	1001
				Area						Medically Important Condition),	immunisation - Not applicable - [1d - n/a		
										Haematochezia (n/a - Not Recovered/Not	- n/a])		
										Resolved - Other Medically Important			
EU-EC-	13/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Condition) Angina pectoris (n/a -	TOZINAMERAN	Not reported	ICSR
10009974482			Healthcare Professional		available	Years	Specified			Recovered/Resolved - Other Medically	[TOZINAMERAN] (S - COVID-19		
				Area						Important Condition), Back pain (n/a -	immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -	.,, 21)		
										Chest pain (n/a -			
										Recovered/Resolved - ),			
										Dizziness (n/a - Recovered/Resolved -			
										),			
										Dyspnoea (n/a - Recovered/Resolved - ),			
										Injection site swelling			
										(n/a - Recovered/Resolved -			
										Insomnia (n/a -			
										Recovered/Resolved -			
										Migraine (n/a -			
										Recovered/Resolved - ),			
										Nausea (n/a - Recovered/Resolved -			
										),			
										Palpitations (n/a - Recovered/Resolved -			
										), Vision blurred (n/a -			
										Recovered/Resolved -			
EU-EC- 10009974868	13/09/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
	12 (22 (222 (		Professional							)	n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10009974972	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	<u>ICSR</u>
			Toressional	/ ii cu						Headache (n/a -	- n/a])		
										Recovered/Resolved - ),			
										Nausea (n/a - Recovered/Resolved -			
										),			
										Pyrexia (n/a - Recovered/Resolved -			
										Vomiting (n/a -			
										Recovered/Resolved -			
EU-EC-	13/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Crying (n/a -	TOZINAMERAN	Not reported	ICSR

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10009975014			Healthcare Professional	European Economic Area	available	Years	Specified			Recovering/Resolving - Other Medically Important Condition), Depressed mood (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Joint range of motion decreased (1d - Recovered/Resolved - Other Medically Important Condition), Mood swings (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Not Resolved - Other Medically Important	COVID-19 immunisation - Not applicable - [1d - n/a		
EU-EC-	13/09/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Condition) Facial paralysis (n/a -	COMIRNATY	Not reported	ICSR
10009975033	13,03,2021	Spontaneous	Professional		available	Years	Specified	remaie		Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	not reported	<u>ICSIX</u>
EU-EC- 10009975228	13/09/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Burning sensation (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						Recovered/Resolved - ), Chills (n/a - Recovered/Resolved - ),	n/a - n/a - [1d - n/a - Intramuscular])		
										Feeling hot (n/a - Recovered/Resolved - )			
EU-EC- 10009975271		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthritis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009975297		Spontaneous	Healthcare Professional	Area		12-17 Years	Adolescent		No	Ageusia (n/a - Recovered/Resolved - ), Anosmia (n/a - Recovered/Resolved - ), Application site pain (n/a - Recovered/Resolved - ), Application site swelling (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Hot flush (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ),	n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009975299		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Headache (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009975312	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [55d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009975450	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Resolved - ) Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
			<u> </u>							Vomiting (n/a - Unknown - )			

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EU-EC- 10009975502	13/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (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- 10009975722	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (1d - Recovered/Resolved - ), Interchange of vaccine products (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Unknown]),  SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX- 024414)] (S - COVID- 19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009975770	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Unknown - )	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])	ICSR
EU-EC- 10009975852	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009975856	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009975867	13/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Palpitations (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009975868	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-		Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Not Specified	Female	No	Axillary mass (n/a - Unknown - Other Medically Important Condition),  Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Subcutaneous abscess (n/a - Unknown - Other Medically Important Condition)		Not reported	ICSR
10009976139		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Headache (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976140		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Presyncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976142	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved - ), Presyncope (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	13/09/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	) Presyncope (n/a -	COMIRNATY	Not reported	ICSR

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10009976147			Professional	Economic Area	available	Years				Unknown - )	[TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009976148	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976271	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Cardiovascular disorder (n/a - Unknown - ),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Chills (n/a - Unknown - ),			
										Fatigue (n/a - Unknown - ),			
										Malaise (n/a - Unknown - ),			
										Myalgia (n/a - Unknown - ),			
										Pyrexia (n/a - Unknown - ),			
										Thrombophlebitis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009976379	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (5d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										)	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009976401	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])	۱۱٫۵۱٫	
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10009976425	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE	ICSR
										Chills (n/a - Recovering/Resolving - ),	applicable - [n/a - n/a - n/a])	MAGNESIUM TRIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]),	
										Fatigue (n/a - Recovering/Resolving - ),		[PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a])	
										Headache (n/a - Recovering/Resolving - ),		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
										Myalgia (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Pain (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10009976455	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 10009976457	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - )	- n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC-	13/09/2021	Spontaneous	Healthcare		Not	12-17	Adolescent	Male	No	Dizziness (n/a -	- n/a]) COMIRNATY	Not reported	ICSR

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10009976460			Professional	Economic Area	available	Years				Unknown - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10009976461	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976462	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976466	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Feeling cold (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976471	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976482	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - ), Presyncope (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -			
EU-EC- 10009976483	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vertigo (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976650	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Unknown - ), Dysentery (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Unknown - ), Neuralgia (n/a -			
										Unknown - ),  Oropharyngeal pain (n/a - Unknown - ),			
										Pyrexia (n/a - Unknown - ),			
										Vaccination site pain (n/a - Unknown - )			
EU-EC- 10009976706	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976707	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vertigo (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976712	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009976713	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC- 10009976719	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Recovered/Resolved -	.,, =1,		
EU-EC- 10009976722	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - ),	- n/a])		
										Nausea (n/a - Recovered/Resolved - ),			
										Presyncope (n/a - Recovered/Resolved - )			
EU-EC- 10009976771	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Lymphadenopathy (n/a - Not Recovered/Not			

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										Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009976790	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR])	Not reported	ICSF
EU-EC- 10009976980	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (n/a - Recovering/Resolving - ), Heart rate increased (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSF
										Recovering/Resolving - )			
EU-EC- 10009977141	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Pain in extremity (2d - Recovered/Resolved - ),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSF
										Pyrexia (2d - Recovered/Resolved -			
EU-EC- 10009977331	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Sleep disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009977333	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009977349	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009977518	13/09/2021	Spontaneous	Non 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 - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC- 10009977771	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (n/a - Recovered/Resolved - ), Arthralgia (n/a - Recovered/Resolved - ), Cough (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										), Nasopharyngitis (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved -			
EU-EC- 10009977780	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009977781	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Panic attack (n/a - Recovered/Resolved - ), Seizure (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009977782	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009977784	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved - ), Nausea (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009977789	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSF
EU-EC- 10009977841	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blood thyroid stimulating hormone decreased (n/a -	- n/a])  COMIRNATY  [TOZINAMERAN] (S - COVID-19	[CICLESONIDE] (C - Asthma - Dose not changed - [n/a -	ICSR

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										Recovering/Resolving - ), Fatigue (2d - Recovering/Resolving - ), Headache (2d - Recovering/Resolving	immunisation - Not applicable - [1d - .3mL - n/a])	160ug - Respiratory (inhalation)]),  [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Autoimmune thyroiditis - Unknown - [n/a - 88ug - Oral])	
										- ), Vaccination site pain (n/a - Recovered/Resolved - ),			
										Weight decreased (n/a - Recovering/Resolving -)			
U-EC- 0009978107	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Generalised tonic- clonic seizure (n/a - Unknown - Other Medically Important Condition), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	10
										Unknown - Other Medically Important Condition)			
J-EC- 0009978605	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	Ī
										), Malaise (3d - Recovered/Resolved - ),			
										Nausea (3d - Recovered/Resolved -			
J-EC- 1009978606	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	]
										Malaise (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
U-EC- 0009978646	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	
J-EC- 0009978693	13/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE, LEVOTHYROXINE SODIUM,	
										Disorientation (20s - Recovered/Resolved - Caused/Prolonged Hospitalisation),		LEVOTHYROXINE SODIUM ANHYDROUS EP] (C - n/a - n/a - [n/a - n/a - n/a])	
										Emotional distress (n/a - Recovered/Resolved - Caused/Prolonged			
										Hospitalisation),  Eye movement disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Fall (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Feeling hot (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											·		1

										Recovered/Resolved - Caused/Prolonged Hospitalisation), Injected limb mobility decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Lethargy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009978984	13/09/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Hospitalisation), Sleep disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) Henoch-Schonlein	TOZINAMERAN	[METHYLPHENIDATE]	ICSR
10009978984			Healthcare Professional	European Economic Area	available	Years	Specified			purpura (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009979017	13/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (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- 10009979077	13/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009979272	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Unknown - ),  Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009979308	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved - ), Palpitations (n/a - Recovered/Resolved - ), Troponin T increased (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009979333		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009979378	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>

										-			
											immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10009979532	13/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009979785	13/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Chills (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009980093	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 10009980117	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - )	- n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 10009980124	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - )	- n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 10009980125	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - )	- n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 10009980594	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved - ), Fatigue (n/a - Recovered/Resolved - ), Feeling cold (n/a -	- n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	13/09/2021	Spontaneous		Non	Not		Not	Male	No	Recovered/Resolved - ), Nasopharyngitis (n/a - Recovered/Resolved - ) Chills (1d - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved - )	TOZINAMERAN	Not reported	ICSR
10009980682			Healthcare Professional	European Economic Area	available	Years	Specified			Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Night sweats (n/a - Not Recovered/Not Resolved - Other Medically Important			
										Condition),  Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009980684	13/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Colinodactyly (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Gait disturbance (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),  Muscle spasms (n/a - Muscle spasms (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovered/Resolved - Other Medically Important Condition),			
										Pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Speech disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10009980959	13/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009980960	13/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Atrial fibrillation (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
										Chest discomfort (n/a - Not Recovered/Not Resolved - ),	- 1(/a])		
										Dyspnoea (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	12/00/2021	Spontaneous	Haalthaara	European	Not	12-17	Adolescent	Fomalo	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY	Not reported	ICCD
10009980984	13/09/2021	Spontaneous	Professional	European Economic Area	available	Years	Adolescent	remale	INO	Unknown - )	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009980985	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009981203	13/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pollakiuria (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling),			
										Thirst (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling),			
										Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Weight decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC- 10009981470	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - n/a])	Not reported	ICSR
EU-EC- 10009981569	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - )	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009981611	13/09/2021	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving  - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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										Injection site pain (n/a - Recovering/Resolving	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009981993	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscle spasms (5d - Recovered/Resolved - ), Vaginal haemorrhage	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										(5d - Recovered/Resolved -	- n/a])		
EU-EC- 10009982143	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (9d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009982158	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Thrombocytopenia (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009982166	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea exertional (n/a - Recovering/Resolving - Other Medically Important Condition), Haemoptysis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]),	Not reported	ICSR
										Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a -	[FLUOXETINE HYDROCHLORIDE] (S - Depression - Dose not changed - [n/a -		
										Recovering/Resolving - Other Medically Important Condition)	30mg - Oral])		
EU-EC- 10009982175	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (1d - Recovered/Resolved - Other Medically Important Condition), Myoclonic epilepsy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										(1d - Recovered/Resolved - Other Medically	Traditioscalary)		
EU-EC- 10009982251	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Influenza like illness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC-	13/09/2021	Spontaneous	Healthcare	Furonean	Not	12-17	Adolescent	Male	No	Herpes zoster (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
10009982300	13,03,2021		Professional			Years	Adolescent	ridic		Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	not reported	10011
EU-EC- 10009982331	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (2d - Recovered/Resolved - ), Chest pain (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										)	1{DF} - Intramuscular])		
EU-EC- 10009982337	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1uCi - Intramuscular])	Not reported	ICSR
EU-EC- 10009982359	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009982366	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009982371	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Recovered/Resolved - ), Influenza like illness (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										- ), Nausea (n/a -	ind amuscular J)		
										Recovering/Resolving - )			
EU-EC-	13/09/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Menstruation delayed	COMIRNATY	Not reported	<u>ICSR</u>

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10009982373			Professional	Economic Area	available	Years				(n/a - Recovered/Resolved With Sequelae - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009982374	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Burning sensation (n/a - Recovering/Resolving -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICS
EU-EC-	12/00/2021	Spontaneous	Haaltheara	European	Not	12-17	Adolescent	Eomalo	No	Recovering/Resolving - )  Dysmenorrhoea (n/a	Intramuscular])  COMIRNATY	Not reported	ICSI
10009982382	13/09/2021	Sportalieous	Professional	Economic Area	available	Years	Adolescent	remale	NO	- Unknown - ),  Menstrual disorder (n/a - Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	<u>1C3</u>
EU-EC- 10009982401	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovering/Resolving - ), Menstrual disorder (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10009982407	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Blepharospasm (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10009982415	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICS
EU-EC- 10009982422	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - )  Dyspnoea (n/a - Recovered/Resolved - ),  Menstrual disorder (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10009982442	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Herpes zoster (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10009982470	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	[DERMATOPHAGOIDES FARINAE EXTRACT, DERMATOPHAGOIDES PTERONYSSINUS EXTRACT] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009982474	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Anxiety (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICS
										Decreased appetite (n/a - Not Recovered/Not Resolved - ),			
										Dyspepsia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Sleep terror (n/a - Not Recovered/Not Resolved - ),			
										Vomiting (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009982476	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eczema (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10009982491	13/09/2021	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	Not reported	ICSI

										ig report			
										(n/a - Not Recovered/Not Resolved - )	2{DF} - Intramuscular])		
EU-EC- 10009982511	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovering/Resolving - ), Dizziness (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSF
										Influenza like illness (n/a - Recovering/Resolving -),	,		
										Menstrual disorder (n/a - Recovering/Resolving -)			
EU-EC- 10009982576	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (1d - Recovered/Resolved - ), Vomiting (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSI
EU-EC- 10009982586	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Recovering/Resolving - ),	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Decreased appetite (n/a - Recovering/Resolving - ),	applicable - [n/a - 1{DF} - Intramuscular])		
										Pyrexia (3d - Recovered/Resolved -			
EU-EC- 10009982616	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (48h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10009982641	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Disturbance in attention (n/a - Recovering/Resolving - ),	applicable - [1d - 1{DF} - Intramuscular])		
										Influenza like illness (2d - Recovered/Resolved - ),			
										Nausea (2d - Recovered/Resolved - ),			
										Vaccination site pain (2d - Recovered/Resolved -			
EU-EC- 10009982888	13/09/2021	Spontaneous	Non 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	ICSF
EU-EC- 10009982894	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009982905	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
EU-EC- 10009982909	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (n/a - Recovering/Resolving - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009982932	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (n/a - Recovered/Resolved - ), Pallor (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSF
										Recovered/Resolved - ), Pyrexia (n/a -	Intramuscular])		

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										Recovered/Resolved - ),			
										Vomiting (n/a - Recovered/Resolved -			
EU-EC- 10009982941	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Influenza like illness (48h - Recovered/Resolved -	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009983020	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Tachycardia (n/a - Not Recovered/Not Resolved - )	applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10009983070	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009983072	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009983092	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009983093	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Intermenstrual bleeding (15d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009983815	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Injection site inflammation (n/a - Recovering/Resolving - ), Injection site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										(n/a - Recovering/Resolving - ), Injection site warmth (n/a -			
										Recovering/Resolving - ), Malaise (n/a -			
										Recovering/Resolving - ),			
										Nausea (1d - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10009983923	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009984853	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009985082	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 40mg - Oral])	ICSR

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										Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged			
										Hospitalisation),  Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Supraventricular tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009985218	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d -	Not reported	ICSR
										Hyperfibrinogenaemia (n/a - Unknown - Caused/Prolonged Hospitalisation),	.3mL - Intramuscular])		
EU EO	12/00/2021					12.17				Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMPUTA		1000
EU-EC- 10009985223	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	INIAIE	No	Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009985256	13/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009985263	13/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Petechiae (5d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Rash erythematous (5d - Recovered/Resolved -	immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10009985902	13/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Body temperature increased (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Chills (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 (1d - Recovered/Resolved - ), Nausea (0d -			
EU-EC-	12/00/2021	Spontaneous	Haalthaara	Furancan	Not	12-17	Not	Female	No	Recovered/Resolved - ) Asthenia (0d -	COMIRNATY	Not reported	ICSR
10009972565	12/09/2021	Spontaneous	Professional	European Economic Area	available	Years	Specified	remale	INO	Recovered/Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Paraesthesia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	.3mL - Intramuscular])		
EU-EC- 10009972570	12/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a3mL - Intramuscular])	[LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE HYDROCHLORIDE] (C - Asthma - n/a - [n/a -	ICSR
										Hyperpyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	]	n/a - n/a])	
										Myopericarditis (n/a -			

							'	I CUIT LIN	LISTI	ig report			
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009972571	12/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a 3mL -	Not reported	ICSR
										Myopericarditis (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Pyrexia (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009972573	12/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Acute abdomen (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Blood sodium decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Hypokalaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009972582	12/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										C-reactive protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10009972596	12/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation)  Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	applicable - [n/a - 1{DF} - Intramuscular])		
										Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009973267	12/09/2021	Spontaneous		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- 10009973336	12/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ageusia (n/a - Not Recovered/Not Resolved - ), Anosmia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Recovered/Not Resolved - )			
EU-EC- 10009973405	12/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (2d - Recovered/Resolved - ),  Body temperature increased (n/a - Recovering/Resolving - ),  Chills (9d - Recovered/Resolved - ),  Fatigue (n/a - Not Recovered/Not Resolved - ),  Headache (2d - Recovered/Resolved - ),  Malaise (n/a - Not Recovered/Not Resolved - ),  Myalgia (2d - Recovered/Resolved - ),  Nausea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Recovered/Not Resolved - )			
EU-EC- 10009973413		Spontaneous	Healthcare Professional		Not available	Years	Not Specified	Female	No	Chills (1h - Recovered/Resolved - ), Fatigue (24h - Recovered/Resolved - ), Headache (8h - Recovered/Resolved - ), Malaise (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - ), Nausea (4h - Recovered/Resolved - ), Pyrexia (24h - Recovered/Resolved - )		Not reported	ICSR
EU-EC- 10009973419	12/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved - ), Injection site pain (2d - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - )		Not reported	ICSR
EU-EC- 10009973439	12/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009973442	12/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (3h	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009973714	12/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (5d - Recovered/Resolved - ), Myalgia (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009973953	12/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (15min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

											applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009973972	12/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	IC
										Headache (n/a - Recovering/Resolving	indaniusculai j)		
EU-EC- 10009968177	11/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	IC
EU-EC- 10009968266	11/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (2d - Recovered/Resolved - ), Chills (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	IC
										Fatigue (2d - Recovered/Resolved -			
										Headache (2d - Recovered/Resolved - ),			
										Malaise (2d - Recovered/Resolved - ),			
										Myalgia (3d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10009968951	11/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	I
										Burning sensation (n/a - Not Recovered/Not Resolved - ),	[n/a3mL - Intramuscular])		
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009970472	11/09/2021	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 AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	<u>10</u>
										Headache (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a - Not			
EU-EC-	11/09/2021	Spontaneous		European	Not	12-17	Not	Female	No	Recovered/Not Resolved - ) Headache (n/a - Not	COMIRNATY	Not reported	10
10009970501			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Resolved - ),  Nausea (n/a - Not Recovered/Not			
EU-EC- 10009970566	11/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - )  Erythema (n/a - Unknown - ),  Injection site oedema (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>I</u> (
										Lymphadenopathy	.3mL - Intramuscular])		

										Pain in extremity (n/a - Unknown - )			
EU-EC- 10009971102	11/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hyperhidrosis (n/a - Recovered/Resolved - ), Influenza like illness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009971158	11/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Unknown - ), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009971170	11/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown - ) Headache (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009972120	11/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Palpitations (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - n/a - [n/a - n/a - n/a]),  [ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a]	ICSR
EU-EC- 10009972274	11/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blood pressure increased (n/a - Not Recovered/Not Resolved - ),  Chills (n/a - Not Recovered/Not Resolved - ),  Heart rate increased (n/a - Not Recovered/Not Resolved - ),  Oropharyngeal pain (n/a - Not Recovered/Not Recovered/Not Resolved - ),  Pyrexia (n/a - Not Recovered/Not	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009957677	10/09/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Paraesthesia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (0d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009957684	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation)  Epistaxis (n/a - Not Recovered/Not Resolved - ),  Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a]),  COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10009957705	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site joint pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009957706	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Anaphylactic shock (n/a - Recovered/Resolved - ), Hypotension (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10009957734	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Type 1 diabetes mellitus (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009957777	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009957796	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ophthalmic herpes zoster (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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EU-EC-	10/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Orthostatic	1{DF} - n/a]) COMIRNATY	Not reported	ICSR
10009957804	10/03/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Adolescent	Maje		intolerance (0d - Recovered/Resolved -	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSK
EU-EC- 10009957807	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Cough (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009957811	10/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - ) Diarrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
EU-EC- 10009957869	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Generalised tonic- clonic seizure (n/a - Recovered/Resolved -	2{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
EU-EC- 10009957938	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site reaction (10d - Not Recovered/Not	1{DF} - n/a])   COMIRNATY   TOZINAMERAN] (S -   n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 10009957967	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - ) Intermenstrual bleeding (2d - Recovered/Resolved - )	- n/a]) 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])	ICSR
EU-EC- 10009957971	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (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- 10009958211	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site erythema (n/a - Not Recovered/Not Resolved - ), Injection site pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009958270	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009958378	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Paraesthesia (1d - Recovered/Resolved - ), Skin discolouration (1d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009958382	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009958394	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Somnolence (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009958404	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10009958431	10/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - ), Diarrhoea (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Limb discomfort (n/a - Recovering/Resolving - ), Muscle spasms (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

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										Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Palpitations (n/a - Recovering/Resolving - )			
EU-EC- 10009958557	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
										Nausea (n/a - Recovered/Resolved - ),	[n/a5mL -		
										Vertigo (n/a - Recovered/Resolved - )			
EU-EC- 10009958947	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site swelling (n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a])		
EU-EC- 10009959385	10/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009960119	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a -	ICSR
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),		n/a - n/a])	
										Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009960202	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - )			
EU-EC- 10009960654	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (5min - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Hyperhidrosis (5min - Recovered/Resolved - )	applicable - [n/a - .3mL - n/a])		
EU-EC- 10009960658	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (2d - Recovered/Resolved - Disabling),	applicable - [n/a - n/a - n/a])		
										Malaise (2d - Recovered/Resolved - Disabling),			
										Myalgia (2d - Recovered/Resolved - Disabling),			
										Nausea (2d - Recovered/Resolved - Disabling),			
										Pyrexia (2d - Recovered/Resolved - Disabling)			
EU-EC- 10009960784	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Dizziness (n/a - Recovered/Resolved - ),			
										Palpitations (n/a - Recovered/Resolved -			
EU-EC- 10009960983	10/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	- n/a])		
										Headache (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Illness (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Limb discomfort (n/a - Recovering/Resolving			
										- Disabling, Other Medically Important Condition)			
EU-EC- 10009961194	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Oropharyngeal pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009961304	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009961325	10/09/2021	Spontaneous	Non 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 - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - )	ICSR
EU-EC- 10009961373	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash pruritic (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- 10009961772	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site erythema (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Intermenstrual bleeding (0d - Recovered/Resolved - ),	li{DF} - n/a])		
										Malaise (3d - Recovered/Resolved - )			
EU-EC- 10009962260	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Abdominal pain (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Chills (7d - Recovered/Resolved - ),	applicable - [n/a -		
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Nausea (14d - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Weight decreased (n/a - Recovering/Resolving			
EU-EC- 10009962325	10/09/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	- )   Chest pain (n/a - Not   Recovered/Not	  COMIRNATY  [TOZINAMERAN] (S -	Not reported	ICSR

			Professional	Area						Resolved - Other Medically Important Condition),	COVID-19 immunisation - n/a - [n/a - n/a - n/a])		
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
Ell EC	10/00/2021		Llas Hisaana	<b>-</b>	Note	12.17	Net	Mala	N	Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMPONATO	Network	ICCD
EU-EC- 10009963072	10/09/2021	Spontaneous		European Economic Area	Not available		Not Specified	Male	No	Chest pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
10009963259		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vertigo (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009963441	10/09/2021	Spontaneous		European Economic Area	Not available		Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (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])	ICSR
										Recovering/Resolving - ), Fatigue (n/a - Not Recovered/Not	1{DF} - n/a])		
										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 - Recovering/Resolving - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009963453	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available		Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (2h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved - ), Headache (n/a - Not	1{DF} - n/a])		
										Recovered/Not Resolved - ), Headache (n/a -			
										Recovering/Resolving - Life Threatening),  Hyperventilation (n/a			
										Recovering/Resolving - Life Threatening), Injection site			
										erythema (n/a - Not Recovered/Not Resolved - ),			
										Injection site inflammation (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										, ,			

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										Malaise (n/a - Not Recovered/Not Resolved - ), Muscle spasms (n/a - Recovering/Resolving - Life Threatening), Myalgia (n/a - Not Recovered/Not Resolved - ), Pyrexia (2h - Recovered/Resolved -			
EU-EC- 10009963509	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (4d - Recovered/Resolved - ), Nausea (4d - Recovered/Resolved - ), Vaccination site pain (n/a - Unknown - ), Vision blurred (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	CIRCADIN 2 MG PROLONGED-RELEASE TABLETS [MELATONIN] (C - Insomnia - n/a - [n/a - n/a - n/a]),  INTUNIV 4 MG PROLONGED-RELEASE TABLETS [GUANFACINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]),  [ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]),  [CITALOPRAM HYDROBROMIDE] (C - Depression - n/a - [n/a - n/a - n/a]),  [DESLORATADINE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]),  [METHENAMINE HIPPURATE] (C - Prophylaxis urinary tract infection - n/a - [n/a - n/a - n/a]),  [METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]),  [QUETIAPINE, QUETIAPINE, QUETIAPINE, CUETIAPINE FUMARATE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009963522	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved - ), Fatigue (8d - Unknown - ), Headache (n/a - Recovered/Resolved With Sequelae - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009964115	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009964396	10/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Heart rate increased (n/a - Recovered/Resolved - ), Hypotension (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DOCONEXENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL ESTERS 90, OMEGA-3- ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009964427	10/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Dehydration (n/a -			
										Unknown - Other Medically Important Condition), Influenza like illness			
										(n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009964433	10/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Neuropathy peripheral (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009964765	10/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Recovering/Resolving - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Fatigue (n/a - Unknown - Disabling),	- Intramuscular])		
										Gastritis (n/a - Unknown - Disabling),			
										Nausea (n/a - Recovering/Resolving - Disabling),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10009965102	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paresis (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009965137	10/09/2021	Spontaneous			Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Not Resolved - ), Lymphadenopathy	1{DF} - n/a])		
										(n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
EU-EC-	10/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Nausea (n/a - Not Recovered/Not Resolved - ) Myocarditis (n/a - Not	COMIDNATY	Not reported	ICSR
10009965292			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	·	
EU-EC- 10009965465	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
EU-EC- 10009965475	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Oligoarthritis (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009965539	10/09/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	- Caused/Prolonged Hospitalisation) Pericarditis (19d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
1000330333			i i oressiOridi	Area	available	lcais	эрссиеч			Other Medically Important Condition)	COVID-19		

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											withdrawn - [1d - 3mL -		
EU-EC- 10009965571	10/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown - Other Medically Important Condition)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009965924	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (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- 10009966715	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10009966719	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009966825	10/09/2021	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 - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009966826	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009966835	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovering/Resolving - ), Visual impairment (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009966863	10/09/2021	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 - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009966908	10/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [30d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009966990	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Influenza like illness (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009967032	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009967042	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Presyncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009967110	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved - )	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009967169		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Immunisation reaction (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009967174	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Deafness (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	10/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Immunisation	COMIRNATY	Not reported	ICSR

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10009967177			Healthcare Professional	Economic Area	available	Years				reaction (n/a - Recovered/Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10009967208	10/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009967480	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Vomiting (2d - Recovered/Resolved -	COMIRNATY	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009967579	10/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved - ), Oropharyngeal pain (6d - Recovered/Resolved - ), Pharyngitis bacterial (5d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009968101	10/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009968201	10/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009968208	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a]),  COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10009968353	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009969499	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Rash erythematous (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009969529	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009969543	10/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site discomfort (n/a - Unknown - ),  Vaccination site inflammation (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009969592	10/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes simplex (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009969634	10/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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Process   Communication   Process   Process   Process   Process   Communication   Process   Process   Communication   Process   Process   Communication   Process   Process   Communication   Process   Process   Communication   Process   Process   Communication   Process   Pr										Pyrexia (n/a -			
		10/09/2021	Spontaneous		Economic		Adolescent	Female	No	Unknown - ),  Nausea (n/a - Unknown - ),  Pyrexia (n/a - Unknown - ),  Vomiting (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	IC
1946	EU-EC- 10009969692	10/09/2021	Spontaneous		Economic		Adolescent	Male	No	Myalgia (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vaccination site inflammation (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	IC
	EU-EC- 10009970088	10/09/2021	Spontaneous	Healthcare	Economic		Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a]),  COMIRNATY [TOZINAMERAN] (S -	Not reported	IC
SUREC (0009943013) Sportaneous ineathrace (arrogem in professional Economic Area (area) (area	EU-EC- 10009942788	09/09/2021	Spontaneous	Healthcare	Economic			Female	No	Recovered/Resolved - Caused/Prolonged	2{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	IC
State   Commission   Peath from European Professional European	EU-EC- 10009942829	09/09/2021	Spontaneous		Economic			Female	No	Recovered/Resolved - Caused/Prolonged Hospitalisation), Partial seizures (11d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	IC
Professional Economic Area wailable Years Specified   Unknown - )   TrOZINAMERANI (5 - COVID-19 immunisation - n/a - [n/a - 3.ml - 1 intramuscular])   Not reported   Iteration   Iteratio	EU-EC- 10009943003	09/09/2021	Spontaneous		Economic			Female	No	Arthralgia (2d - Recovered/Resolved - ), Asthenia (2d -	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	IC
Professional Economic Area   Professional Eco	EU-EC- 10009943015	09/09/2021			Economic			Male	No		[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	IC
Spontaneous   Healthcare Professional   European (2009)   Poly	EU-EC- 10009945015	09/09/2021	Spontaneous		Economic			Female	No	Recovered/Resolved With Sequelae - ), Headache (n/a - Recovered/Resolved With Sequelae - ), Vertigo (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	IC
Healthcare Professional Recovered/Not Resolved - ),  Healthcare Professional Recovered/Not Resolved - ),  Headache (n/a - Not Recovered/Not Resolved - ),  Hyperhidrosis (n/a - Not Recovered/Not Resolved - ),  Injection site pain (n/a - Not Recovered/Not Resolved - ),  Nausea (n/a - Not Recovered/Not Resolved - ),  Pain in extremity (n/a - Not Recovered/Not Resolved - ),  Pain in extremity (n/a - Not Recovered/Not Resolved - ),	EU-EC- 10009945094	09/09/2021	Spontaneous		Economic			Female	No	Arthralgia (n/a - Recovered/Resolved - ), Insomnia (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	IC
Injection site pain (n/a - Not Recovered/Not Resolved - ),  Nausea (n/a - Not Recovered/Not Resolved - ),  Pain in extremity (n/a - Not Recovered/Not Resolved - ),	EU-EC- 0 10009945157	09/09/2021	Spontaneous	Healthcare	Economic			Female	No	Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Hyperhidrosis (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	IC
- Not Recovered/Not Resolved - ),										Injection site pain (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not			
										- Not Recovered/Not			49

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		_								Recovered/Not Resolved - )			
EU-EC- 10009945184	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood creatine phosphokinase increased (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
										Dyspnoea (n/a - Recovering/Resolving - ),			
										Rhabdomyolysis (n/a			
										Recovering/Resolving - ),			
										Tremor (n/a - Recovering/Resolving - )			
EU-EC- 10009945254	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Papilloedema (n/a - Unknown - Other Medically Important Condition), Visual acuity reduced (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
										Visual field defect (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009945263	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cerebral venous thrombosis (n/a - Unknown - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a3mL -	Not reported	ICSR
EU-EC- 10009945273	09/09/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Dehydration (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
			Professional				'			- Disabling),  Headache (n/a - Recovering/Resolving - Disabling),	n/a - Not applicable - [n/a - n/a - n/a])		
										Hyperpyrexia (n/a - Recovering/Resolving - Disabling),			
										Pruritus (n/a - Recovering/Resolving - Disabling)			
EU-EC- 10009945285	09/09/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Axillary pain (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Not Recovered/Not Resolved - ), Chest pain (n/a - Not Recovered/Not	1{DF} - Intramuscular])		
										Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10009945300	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Venous thrombosis (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009945338	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysentery (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
										Fatigue (3d - Recovered/Resolved - ),	[n/a3mL - Intramuscular])		
										Feeling cold (3d - Recovered/Resolved - ),			
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										), Pyrexia (3d - Recovered/Resolved -			
EU-EC- 10009945408	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Unknown - ), Chest pain (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
										Headache (n/a - Unknown - ),	indamuscular j)		
										Monoparesis (n/a - Unknown - ),			ICSI a
										Pain in extremity (n/a - Unknown - ),			
EU-EC-	09/09/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Paraesthesia (n/a - Unknown - ) Asthenia (n/a -	COMIRNATY	Not reported	ICS
10009945766			Healthcare Professional	Economic Area	available	Years	Specified			Recovering/Resolving - ),  Body temperature increased (n/a - Recovering/Resolving - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Diarrhoea (n/a - Recovering/Resolving - ),			
										Dizziness (n/a - Recovering/Resolving - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Oversensing (n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10009946246	09/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
EU-EC- 10009946290	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Unknown - ), Fatigue (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10009946337	09/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac flutter (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN	[LYMECYCLINE] (C - Acne - n/a - [89d - n/a - n/a])	
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009946785	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
EU-EC- 0 10009946876	09/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition),	·,, «,j)		
										Feeling cold (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Loss of consciousness			

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										Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral coldness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009947292	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009947298	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009947299	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009947301	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009947305	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Circulatory collapse (n/a - Unknown - ), Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009947415	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown - )  Extensive swelling of vaccinated limb (n/a - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving - Disabling),	applicable - [n/a - n/a - n/a])		
										Headache (n/a - Recovering/Resolving - Disabling),			
										Lymphadenopathy (n/a - Recovering/Resolving - Disabling),			
										Myalgia (n/a - Recovering/Resolving - Disabling)			
EU-EC- 10009947580		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Muscle spasms (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009947586		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Circulatory collapse (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009947812	09/09/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Juvenile idiopathic arthritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009948093	09/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009948129	09/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Malaise (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009948224	09/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	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

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EU-EC- 10009948259	09/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition), Fall (n/a - Recovered/Resolved - ), Presyncope (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10009948629	09/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (6d - Recovered/Resolved - ), Heavy menstrual bleeding (2d - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10009948881	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10009948903	09/09/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - ) Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10009948904	09/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition),  Chest pain (n/a - Recovering/Resolving - ),  Dyspnoea (n/a - Unknown - ),  Heart rate increased (n/a - Unknown - ),  Pain in extremity (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10009949045	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eyelid oedema (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10009949805	09/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (1d - Recovered/Resolved - )	COMIRNATY	NOT AVAILABLE (C - n/a - n/a - n/a - n/a - n/a - n/a - n/a],  [ASCORBIC ACID, PARACETAMOL, ANHYDROUS CAFFEINE] (C - n/a - n/a]),  [PARACETAMOL, ACETYLSALICYLIC ACID, CAFFEINE] (C - n/a - n/a - n/a - n/a]),  [XYLOMETAZOLINE HYDROCHLORIDE] (C - n/a	ICS
EU-EC- 10009949807	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Nausea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Recovering/Resolving			

											applicable - [n/a -		
EU-EC- 10009949853	09/09/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not	1{DF} - n/a])   COMIRNATY   [TOZINAMERAN] (S -   n/a - n/a - [1d - n/a -	Not reported	ICSR
EU-EC- 10009949896	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - ) Diarrhoea (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10009950523	09/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Flushing (n/a - Recovered/Resolved - ), Skin abrasion (1d - Unknown - ), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10009950935	09/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10009950966	09/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009951059	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Heavy menstrual bleeding (n/a - Recovered/Resolved - ), Polymenorrhoea (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009951067	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysphagia (n/a - Recovered/Resolved - ), Ear pain (n/a - Recovered/Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009951069	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved - ), Chills (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009951070	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Pyrexia (n/a - Recovered/Resolved -			
EU-EC- 10009951171	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
EU-EC- 10009951317	09/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),  Demyelination (n/a - Unknown - Caused/Prolonged Hospitalisation),  Dysuria (n/a - Unknown - Caused/Prolonged Hospitalisation),  Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation),  Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),  Myelitis (n/a - Unknown - Caused/Prolonged Hospitalisation),  Nervous system disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),  Paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation),  Paraplegia (n/a - Unknown - Caused/Prolonged Hospitalisation),  Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation),  Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation),  Spinal cord haemorrhage (n/a - Maemorrhage (n/a - Spinal cord haemorrhage (n/a - Spinal cor		Not reported	ICSI
										Unknown - Caused/Prolonged Hospitalisation),  Spinal vessel congenital anomaly (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009951367	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (5min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10009951368	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (5min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10009951577	09/09/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10009951603	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10009951682	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Balance disorder (36h - Recovered/Resolved - Life Threatening), Dizziness (36h - Recovered/Resolved -		Not reported	ICSF

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										Life Threatening),  Eye pain (36h - Recovered/Resolved -	1{DF} - Intramuscular])		
										Life Threatening), Headache (36h - Recovered/Resolved - Life Threatening),			
										Hyperhidrosis (36h - Recovered/Resolved - Life Threatening),			
										Lethargy (36h - Recovered/Resolved - Life Threatening),			
										Photophobia (36h - Recovered/Resolved - Life Threatening),			
EU-EC-	00/00/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Fomalo	No	Pyrexia (36h - Recovered/Resolved - Life Threatening)	COMIRNATY	Not reported	ICSR
10009951779	09/09/2021	Sportalieous	Healthcare Professional	Economic	available	Years	Adolescent	remale		bleeding (n/a - Recovering/Resolving - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSK
EU-EC- 10009951790	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Epistaxis (n/a - Not Recovered/Not Resolved - ),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Recovering/Resolving - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Recovering/Resolving - )			
EU-EC- 10009951855	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009951909	09/09/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Nausea (2wk - Recovering/Resolving - ),	Intramuscular])  COMIRNATY  [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - )	applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10009952331	09/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009952416	09/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved - )	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009952428	09/09/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Asthenia (n/a - Not Recovered/Not Resolved - ),	immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
										Chest pain (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - )			

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