## 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])	ICSR Form
EU-EC- 10010365394	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Haemorrhage subcutaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vasculitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010365452	19/10/2021	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 -	Not reported	ICSR
										Fatigue (72h - Recovered/Resolved - ),	1{DF} - n/a])		
										Malaise (72h - Recovered/Resolved - ),			
										Myalgia (48h - Recovered/Resolved - ),			
										Nausea (72h - Recovered/Resolved - ),			
										Uterine pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010365458	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL	Not reported	<u>ICSR</u>
										Cough (n/a - Recovered/Resolved - ),	- Intramuscular])		
										Headache (n/a - Recovered/Resolved - ),			
										Menstruation delayed (n/a - Recovered/Resolved - ),			
										Nausea (n/a - Recovered/Resolved - ),			
										Rhinorrhoea (n/a - Recovered/Resolved - )			
EU-EC- 10010365719	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010365808	19/10/2021	Spontaneous	Healthcare	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 -	Not reported	ICSR
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a])		
EU-EC- 10010365884	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash papular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	1	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Urticaria (n/a - Not	COMIRNATY	Not reported	ICSR 1/G

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10010366084			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010366135	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Henoch-Schonlein purpura (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Rash maculo-papular (n/a - Recovered/Resolved - ),			
										Vomiting (n/a - Recovered/Resolved - )			
EU-EC- 10010366161	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Immunisation reaction (n/a - Recovered/Resolved - ),	Intramuscular])		
										Renal pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010366299	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010366446	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ANTICONCEPTIEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010366874	19/10/2021	Spontaneous		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 - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010366884	19/10/2021	Spontaneous		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 -	Not reported	ICSR
										Chills (1d - Recovered/Resolved - ),	1{DF} - n/a])		
										Fatigue (7d - Recovered/Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Hyperpyrexia (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (2d - Recovered/Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010366907	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Malaise (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a])		
EU-EC- 10010367164	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010367208	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (n/a - Recovered/Resolved - ), Feeling abnormal (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- ), Heart rate increased (n/a - Recovered/Resolved - ),			
										Syncope (n/a - Recovered/Resolved - Other Medically			

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										Important Condition),			
										Tremor (n/a - Recovered/Resolved - )			
EU-EC- 10010367328	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]),	Not reported	ICSR
										Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	1{DF} - n/a])		
EU-EC- 10010367334	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bruxism (1min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Eye movement disorder (1min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Muscle spasms (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010368076	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Recovering/Resolving - ), Disorientation (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010368107	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ), Fatique (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved - ), Malaise (n/a - Not	T(DI) INDI)		
										Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not			
EU-EC- 10010368276	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Resolved - ) Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10010368562	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition),	n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Nasopharyngitis (n/a	17-17		
										Recovering/Resolving Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010368723	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

											Not applicable - [1d - n/a -		I
EU-EC- 10010368726	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cutaneous vasculitis (n/a - Recovering/Resolving - Other Medically	n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL	Not reported	ICSR
EU-EC- 10010368830	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Amenorrhoea (1mo - Recovered/Resolved - )	- Intramuscular])  COMIRNATY  [TOZINAMERAN] (S -  COVID-19 immunisation -  Not applicable - [n/a -  1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010368835	19/10/2021	Spontaneous	Healthcare	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- 10010368846	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),  Dysmenorrhoea (n/a - Recovering/Resolving - ),  Fatigue (n/a - Not Recovered/Not Resolved - ),  Headache (n/a - Not Recovered/Not Resolved - ),  Malaise (n/a - Not Recovered/Not Resolved - ),  Myalgia (n/a - Not Recovered/Not Resolved - ),  Myalgia (n/a - Not Recovered/Not Resolved - ),  Nausea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
EU-EC- 10010343070	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Not Recovered/Not Recovered/Not Resolved - ) Multisystem inflammatory syndrome in children (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a - [n/a - 40mg - Oral]),  INOVELON [RUFINAMIDE] (C - n/a - n/a - [n/a - 40mL - Oral]),  [BACLOFEN] (C - Quadriplegia - n/a - [n/a - 15mg - Oral]),  [CLOBAZAM] (C - Epilepsy - n/a - [n/a - 7.5mg - Oral]),  [OXCARBAZEPINE] (C - Epilepsy - n/a - [n/a - 1200mg - Oral])	
EU-EC- 10010343075	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation),  Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)  Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Myopericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	RITUXIMAB [RITUXIMAB] (C - n/a - n/a - )	ICSR
EU-EC-	18/10/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Chest discomfort	COMIRNATY	Not reported	ICSR
10010343242			Professional	Economic Area	available	Years				(n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])		

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:U-EC- 0010343246	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hedically Important Condition)  Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	IC
										Condition), Myasthenia gravis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important			
J-EC- 0010343339	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Headache (n/a - Recovering/Resolving - ), Injection site pain (n/a - Recovered/Resolved - ), Night sweats (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>IC</u>
I-EC-	18/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Recovering/Resolving - ) Pain in extremity (7d	COMIRNATY	Not reported	IC
010343731			Professional		available	Years	Specified			Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
I-EC- 010343805	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovering/Resolving - ), Irritability (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	10
										Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - )			
I-EC- 010343852	18/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	Ī
J-EC- 0010343925	18/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>I</u>
										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Eye movement disorder (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hyperventilation (n/a			
										Recovered/Resolved - Other Medically Important Condition),			
										Lip swelling (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Loss of consciousness (n/a - 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			

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										Condition),			
										Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Tremor (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010344330	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a -	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved - ),	n/a - n/a])		
										Feeling hot (1d - Recovered/Resolved - ),			
										Injection site pain (1d - Recovered/Resolved			
EU-EC- 10010344336	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010345062	18/10/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Area						- Life Threatening), Headache (n/a - Recovering/Resolving - Life Threatening),	Not applicable - [1d - n/a - n/a])		
										Hepatic enzyme increased (n/a - Recovering/Resolving - Life Threatening),			
										Myocarditis (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition),			
										Pneumonitis (n/a - Recovering/Resolving - Life Threatening),			
										Pyrexia (n/a - Recovering/Resolving - Life Threatening),			
										Rash (n/a - Recovering/Resolving - Life Threatening),			
										Rash erythematous (n/a - Recovering/Resolving - Life Threatening)			
EU-EC- 10010345071	18/10/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
10010313071				Economic Area	available	rears	Эрестей			Recovering/Resolving - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC- 10010345228		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	-)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010345302	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Disturbance in attention (1d - Recovered/Resolved - Disabling),	Not applicable - [n/a - n/a - n/a])		
										Exercise tolerance decreased (1d - Recovered/Resolved - Disabling),			
										Fatigue (1d - Recovered/Resolved - Disabling),			
										Headache (1d - Recovered/Resolved - Disabling),			
										Injection site reaction (1d - Recovered/Resolved - Disabling),			
										Myalgia (1d - Recovered/Resolved - Disabling),			
										Pyrexia (1d -			

										Recovered/Resolved - Disabling)			
EU-EC- 10010345315	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (25d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Headache (25d - Not Recovered/Not Resolved - ),	11/a - 11/a])		
										Lymphadenopathy (3d - Not			
										Recovered/Not Resolved - ),			
										Myalgia (5d - Recovered/Resolved - )			
EU-EC- 10010345320	18/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
			Professional	Aled						- ), Feeling cold (0d - Recovered/Resolved - ),	Immunisation - n/a - [n/a - n/a - n/a])		
										Headache (0d - Recovered/Resolved - ),			
										Injection site pain			
										(4d - Recovered/Resolved - ),			
										Nausea (0d - Recovered/Resolved - ),			
										Vaccination site reaction (3d - Recovered/Resolved -)			
EU-EC- 10010345489	18/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Abnormal faeces (4d	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
			Professional	Area						Recovering/Resolving - ),	Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Diarrhoea (4d - Recovering/Resolving - )			
EU-EC- 10010345668	18/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
			Professional	Area						- Disabling), Fatigue (1d - Recovered/Resolved	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										- Disabling),  Headache (1d - Recovered/Resolved			
										- Disabling), Injection site reaction (1d - Recovered/Resolved			
										- Disabling), Myalgia (1d -			
										Recovered/Resolved - Disabling),			
										Pyrexia (1d - Recovered/Resolved - Disabling)			
EU-EC- 10010345738	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation,	COVID-19 immunisation -	Not reported	ICSF
										Other Medically Important Condition)	Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010345900	18/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Pericarditis (n/a -	n/a])		
										Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010345914	18/10/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
				Economic Area			·			Recovered/Resolved - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010345919	18/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Fall (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
,				Economic Area						- Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Gait inability (0d - Recovered/Resolved - ),			

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										Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - ),			
										Pallor (0d - Recovered/Resolved - ),			
										Presyncope (n/a - Recovered/Resolved - )			
EU-EC- 10010346183	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (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- 10010346357	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Iridocyclitis (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010346539	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010346829	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010346889	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Menstruation irregular (n/a - Recovering/Resolving - )			
EU-EC- 10010346991	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	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- 10010346992	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (25d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010347025	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Injection site pain (0d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rhinorrhoea (1d - Recovered/Resolved - )			
EU-EC- 10010347210		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Rash pruritic (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010347244	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving - ),			
										Headache (n/a - Recovering/Resolving - ), Malaise (n/a -			
										Recovering/Resolving - )			
EU-EC- 10010347516	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Fatigue (2d - Not Recovered/Not Resolved - ),			
										Injection site pain (4d - Recovered/Resolved - ),			
										Malaise (3d - Recovering/Resolving - ),			
										Pyrexia (0d -			

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										Recovered/Resolved - )			
EU-EC- 10010347651	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010347657	18/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
FIL FO	10/10/2021	Constant	New	5	Note	12.17	0.4-1	Farada	N-	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPANY	Network	100
EU-EC- 10010347916	10/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remaje	No	Dizziness (n/a - Recovering/Resolving - ), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovering/Resolving - ), Hunger (n/a - Recovering/Resolving			
										Malaise (n/a - Recovering/Resolving			
EU-EC- 10010348428	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Limb discomfort (31d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Malaise (31d - Not Recovered/Not Resolved - ), Sleep disorder (31d -			
FIL FO	10/10/2021			-		10.17				Not Recovered/Not Resolved - )	COMPANY		100
EU-EC- 10010348606	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved -), Dizziness (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovered/Resolved - ), Headache (0d -			
										Recovered/Resolved - ), Nausea (0d - Recovered/Resolved			
										- ), Pain in extremity (0d - Recovered/Resolved			
EU-EC- 10010348831	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- )   Menstrual disorder   (22d -   Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a -	Not reported	ICSF
EU-EC- 10010348842	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving	n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010348982	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Lymphadenopathy (2d - Recovered/Resolved -),			
										Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10010349455	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010349661	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Abnormal faeces (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a -	Not reported	ICS
			TOTESSIONAL	AIC C						- ), Vomiting (2d - Recovered/Resolved	n/a - Subcutaneous])		
EU-EC- 10010349779	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010350051	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSE

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										Medication overuse headache (2d -	Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Resolved - ), Myalgia (2d - Recovered/Resolved			
										Pyrexia (2d - Recovered/Resolved			
U-EC- 0010350114	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site pain (4d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
U-EC- 0010350192	18/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0010350215	18/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ), Rhabdomyolysis (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSF</u>
										- Recovering/Resolving - Other Medically Important Condition)			
J-EC- 0010350227	18/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition)			
U-EC- 0010350251	18/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (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	ICSF
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Lethargy (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically			
										Important Condition),			

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										Medically Important Condition)			
EU-EC- 10010350475	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Male	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Medically Important			
EU-EC- 10010350533	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010350912	18/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Grip strength decreased (n/a - Unknown - Caused/Prolonged Hospitalisation),	2		
										Mydriasis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010351169	18/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (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
										Troponin increased (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010351872	18/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Nasal congestion (n/a - Unknown - Other Medically Important Condition),			
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Suspected COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010352135	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			

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EU-EC- 10010352395	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymph node pain (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010352472	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - )  Malaise (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10010352481	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tonic clonic movements (n/a - Recovered/Resolved - Life Threatening)	1{DF} - Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10010352563	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown - )	1{DF} - Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSE
EU-EC- 10010352592	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (48h - Recovered/Resolved - ),	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSE
										Asthenia (48h - Recovered/Resolved - ), Headache (48h -	and an accuracy		
										Recovered/Resolved - ), Malaise (48h - Recovered/Resolved			
EU-EC- 10010352780	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010352920	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010352956	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea exertional (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
										Immunisation reaction (n/a - Not Recovered/Not Resolved - ),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010353015	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (12h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010353042	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (n/a - Recovering/Resolving -), Immunisation	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										reaction (n/a - Recovering/Resolving - ), Myalgia (n/a -			
EU-EC- 10010353231	18/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving - ) Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	TOZINAMERAN	Not reported	ICSR
										Blood pressure decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	n/a])		
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010353300	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Chest pain (1d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Myocarditis (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S -	Not reported	ICSF
										Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010353486	18/10/2021	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 reported	ICSR
						1	1	I		I	I		1

											Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010353878	18/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (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
										Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Disturbance in attention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Irritability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lymph node 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),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sleep disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010354003	18/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Life Threatening),  Erythema (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Induration (n/a - Recovering/Resolving - ),			
										Pneumonia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pruritus (n/a - Recovering/Resolving - ),			

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										Rash (n/a - Recovering/Resolving - ),			
										Rash erythematous			
										(n/a - Recovering/Resolving  - ),			
										Swelling (n/a - Recovering/Resolving - ),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Urticaria (n/a - Recovering/Resolving - )			
EU-EC- 10010354054	18/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010354455	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Unknown - ), Myalgia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010354486	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			riolessional	Alea						Malaise (1d - Recovered/Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])		
										Nausea (1d - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovering/Resolving - ),			
										Visual impairment (n/a - Recovered/Resolved - )			
EU-EC- 10010354537	18/10/2021	Spontaneous			Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Unknown - ), Rash (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a3mL -	Not reported	ICSR
EU-EC- 10010354820	18/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	- )   Menstrual disorder   (n/a - Unknown - )	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area			·				COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010354842	18/10/2021	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	<u>ICSR</u>
EU-EC- 10010354990	18/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010355128	18/10/2021	Spontaneous	Healthcare	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 -	Not reported	ICSR
										Hyperpyrexia (72h - Recovered/Resolved - ),	1{DF} - n/a])		
										Nausea (42h - Recovered/Resolved - )			
EU-EC- 10010355523	18/10/2021	Spontaneous	Healthcare	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- 10010355531	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010355545	18/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiogenic shock (n/a - Recovered/Resolved - Other Medically	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC-	18/10/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Important Condition) Drug eruption (3d -	n/a]) COMIRNATY	Not reported	ICSR

Healthcare   Economic   Professional   Area   Professional   Area   Professional   Area   Professional   Economic   Professional   Professional   Economic   Professional   Economic   Professional   Professional   Economic   Professional   Professional   Professional   Professional   Professional   Pro	J.11.2022 I	11.30							Run	Line i	Listing Report			
Substitute   Sub	10010355555			Professional	Economic	available	Years	Specified			- Other Medically Important	COVID-19 immunisation - Not applicable - [1d - n/a -		
No.   Part   P											Unknown - Other Medically Important			
Public   P											Unknown - Other Medically Important			
DEC											Recovered/Resolved - Other Medically Important			
											Recovered/Resolved - Other Medically Important Condition)			
Professional   Economic   Area		18/10/2021	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
Autonithmentory   Consequence   National Processions   National Pr		18/10/2021	Spontaneous		Economic			Adolescent	Male	No	Recovered/Resolved - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL	Not reported	ICSF
Recovered Recovered   Council Recovered Reco											disease (n/a - Recovering/Resolving - Caused/Prolonged	,		
Recovered/Resolved   County-											Recovered/Resolved - Caused/Prolonged			
EU-EC- 10010355730 18/10/2021 Spontaneous Mon Mon Healthcare Economic Professional Area Scoromic Profe											Recovered/Resolved - Caused/Prolonged			
Healthcare   Economic Professional											Recovered/Resolved - Caused/Prolonged Hospitalisation)			
Professional Area available Area ava	10010355663			Healthcare Professional	Economic					No		[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010355739 18/10/2021 Spontaneous Healthcare European Professional Economic Area    18/10/2021 Spontaneous Healthcare European Professional Economic Area    18/10/2021 Spontaneous Non Healthcare Economic Professional Area    18/10/2021 Spontaneous Non Healthcare Professional Area    Non Cominnary (COMIRNATY (COUD-19 immunisation - Not applicable - [id - n/a - n/a])    Not reported    18/10/2021 Spontaneous Non Healthcare Professional Area    Non Cominnary (COMIRNATY (COUD-19 immunisation - Not applicable - [id - n/a - n/a])    Not reported    18/10/2021 Spontaneous Non Healthcare Professional Area    Non Cominnary (COMIRNATY (COUD-19 immunisation - Not applicable - [id - n/a - n/a])    Not reported    18/10/2021 Spontaneous Non Healthcare Professional Area    Non Coud-19 immunisation - Not applicable - [id - n/a - n/a]    Not reported    19/10/2021 Spontaneous Non Area    Not reported    19/10/2021 Spontaneous Non Area    Not applicable - [id - n/a - n/a]    Not reported    19/10/2021 Spontaneous Non Area    Not applicable - [id - n/a - n/a]    Not reported    19/10/2021 Spontaneous Non Area    Not applicable - [id - n/a - n/a]    Not reported    19/10/2021 Spontaneous Non Area    Not applicable - [id - n/a - n/a]    Not reported    19/10/2021 Spontaneous Non Area    Not applicable - [id - n/a - n/a]    Not applicab		18/10/2021	Spontaneous		Economic			Adolescent	Male	No	Unknown - ), Nausea (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
EU-EC- 10010355739   18/10/2021   Spontaneous   Healthcare   Professional   European   Not available   Years   Adolescent   Female   No   Cough (1d - Recovered/Resolved -)   TOZIINAREAN) (5 - COUID-19 immunisation - Not applicable - [1d - n/a - Not														
EU-EC- 10010355769  Teu-Ec- 1001035769  Teu-Ec- 1001035776  Teu-Ec- 1001035777  Teu-Ec- 1001035777  Teu-Ec- 1001035777  Teu-Ec		18/10/2021	Spontaneous		Economic			Adolescent	Female	No	Cough (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC- 10010355769 18/10/2021 Spontaneous Professional Professional Realthcare Recovered/Resolved Professional Realthcare Professional Realthcare Recovered/Resolved Professional Realthcare Professional Realthcare Recovered/Resolved Professional Recovered/Resolve											Recovered/Resolved	n/a])		
EU-EC- 10010355769 18/10/2021 Spontaneous Non Healthcare Professional Reaction Area Professional Recovered/Resolved - ),  Diarrhoea (6d - Recovered/Resolved - ),  Diarrhoea (6d - Recovered/Resolved - ),  Diarrhoea (6d - Recovered/Resolved - ),  Headache (6d - Recovered/Resolved - ),  Headache (6d - Recovered/Resolved - ),  Intermenstrual bleeding (6d - Recovered/Resolved - ),  Intermenstrual b											Recovered/Resolved - ),  Vomiting (1d -			
Bone pain (6d - Recovered/Resolved - ),  Diarrhoea (6d - Recovered/Resolved - ),  Dizziness (6d - Recovered/Resolved - ),  Dizziness (6d - Recovered/Resolved - ),  Headache (6d - Recovered/Resolved - ),  Intermenstrual bleeding (6d - Recovered/Resolved - ),  Intermenstrual bleeding (6d - Recovered/Resolved - ),		18/10/2021	Spontaneous					Adolescent	Female	No	- ) Asthenia (6d -		Not reported	ICSR
Diarrhoea (6d - Recovered/Resolved - ), Dizziness (6d - Recovered/Resolved - ), Headache (6d - Recovered/Resolved - ), Intermenstrual bleeding (6d - Recovered/Resolved - ), Recovered/Resolved - ),				Professional	Area						Bone pain (6d - Recovered/Resolved	Not applicable - [1d - n/a -		
Recovered/Resolved - ), Headache (6d - Recovered/Resolved - ), Intermenstrual bleeding (6d - Recovered/Resolved - ), Recovered/Resolved - ),											Diarrhoea (6d - Recovered/Resolved			
Recovered/Resolved - ), Intermenstrual bleeding (6d - Recovered/Resolved - ),											Recovered/Resolved			
bleeding (6d - Recovered/Resolved - ),											Recovered/Resolved			
											bleeding (6d - Recovered/Resolved - ),			
(6d - Recovered/Resolved											(6d -			

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										- ), Malaise (6d - Recovered/Resolved - ),			
										Pyrexia (6d - Recovered/Resolved			
EU-EC- 10010355959	18/10/2021	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- 10010355962	18/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Blood pressure decreased (n/a - Recovered/Resolved - ),			
										Dizziness (n/a - Recovering/Resolving - ),			
										Feeling abnormal (n/a - Recovering/Resolving - ),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (0d - Recovered/Resolved - )			
EU-EC- 10010356115	18/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010356227	18/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (2h - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Lip swelling (n/a - Recovered/Resolved - ),			
										Malaise (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Vaccination site pain (n/a - Recovered/Resolved - ),			
										Wheezing (n/a - Recovered/Resolved - )			
EU-EC- 10010356267	18/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (4h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (1d - Recovered/Resolved - )			
EU-EC- 10010356275	18/10/2021	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- 10010356573	18/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC-	17/10/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	COVID-19 (n/a -	1{DF} - n/a]) COMIRNATY	Not reported	<u>ICSR</u>

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10010342227			Professional	Economic Area	available	Years				Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010342234	17/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010342427	17/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Puncture site pain (n/a - Recovering/Resolving -),	T(B) Intumasculary		
EU-EC-	17/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Vomiting (n/a - Recovering/Resolving - ) Chills (0d -	COMIRNATY	Not reported	ICSR
10010342435				Economic Area	available	Years	Specified			Recovered/Resolved - ), Fatigue (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Resolved - ), Headache (n/a - Recovering/Resolving			
										- ), Injection site pain (n/a - Recovering/Resolving			
										- ), Malaise (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (0d - Recovered/Resolved - )			
EU-EC- 10010342607	17/10/2021	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- 10010342718	17/10/2021	Spontaneous	Healthcare	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
											[NOT AVAILABLE] (S - n/a - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010342786	17/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Dizziness (10min - Recovered/Resolved - ),	COMIRNATY	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Injection site pain (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a - Not			
EU-EC-	17/10/2021	Spontaneous		European	Not	12-17 Years	Adolescent	Male	No	Recovered/Not Resolved - ) COVID-19 (n/a -	COMIRNATY	Not reported	ICSR
10010342811			Professional	Economic Area	available	Years				Unknown - Other Medically Important Condition), Vaccination failure	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
										(n/a - Unknown -			

										_isting report			
										Other Medically Important Condition)			
EU-EC- 10010342892	17/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010343041	17/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010343044	17/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Face oedema (n/a - Recovered/Resolved - ), Urticaria (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSE
EU-EC-	17/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Resolved - )  Dysmenorrhoea (n/a	COMIRNATY	[IBUPROFEN] (C - n/a - n/a	ICSR
10010343193	17,10,2021	Sportanicous	Healthcare	Economic Area	available	Years	Specified	i emaje		- Not Recovered/Not Resolved - ), Fatigue (1d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	- [n/a - n/a - n/a])	100.
										Recovered/Resolved			
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),			
										Malaise (4d - Recovered/Resolved - ),			
										Myalgia (1d - Recovered/Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10010343206	17/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010343225	17/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (14d - Unknown - )		Not reported	ICSR
EU-EC- 10010339837	16/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Urticaria (n/a - Not Recovered/Not Resolved - )	Intramuscular])		
EU-EC- 10010339924	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010339932	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a -	Not reported	ICSR
EU-EC- 10010340092	16/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010340217	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - )	1{DF} - Intramuscular])		
EU-EC- 10010340298	16/10/2021	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 - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010340507	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	<u>ICSR</u>
tns://dan.ei		o outonstr	tion/one							Heavy menstrual bleeding (n/a -			18/6

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										Recovering/Resolving - )			
EU-EC- 10010340984	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Resolved - ),  Vomiting (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010340991	16/10/2021	Spontaneous	Healthcare	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	ICSF
EU-EC- 10010340997	16/10/2021	Spontaneous	Healthcare	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- 10010341001	16/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - ), Fatigue (2d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010341443	16/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Headache (6d - Recovered/Resolved - ), Heavy menstrual bleeding (6d - Recovered/Resolved - ), Polymenorrhoea (6d - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010341471	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC-	16/10/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY	Not reported	ICSF
10010341474			Professional	Economic Area	available	Years				Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010341475	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010341515	16/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010341663	16/10/2021	Spontaneous	Healthcare	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- 10010341746	16/10/2021	Spontaneous	Healthcare	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- 10010341788	16/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (37d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010342053	16/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (8h - Recovered/Resolved - ), Fatigue (1d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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										Menstrual disorder (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (2d - Recovered/Resolved - ),			
										Pyrexia (8h - Recovered/Resolved			
EU-EC- 10010342085	16/10/2021	Spontaneous	Healthcare	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 - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010329286	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Headache (2d - Recovered/Resolved -), Injection site pain			
										(2d - Recovered/Resolved - )			
EU-EC- 10010329287	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Headache (2d - Recovered/Resolved - ),			
										Injection site pain (2d - Recovered/Resolved - )			
EU-EC- 10010329288	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
										Injection site pain (2d - Recovered/Resolved	n/a - [n/a - n/a - Intramuscular])		
										- ), Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10010329509	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
				7.1.04						Pyrexia (n/a - Recovered/Resolved - )	Not applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10010329512	15/10/2021	Spontaneous	Non Healthcare Professional				Not Specified	Female	No	Injection site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010329530	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10010329552	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug -	Not reported	<u>ICSR</u>
										- Recovered/Resolved	Intramuscular])		
EU-EC- 10010329630	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (3d - Recovered/Resolved - ), Diarrhoea (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - ), Fatigue (3d - Recovered/Resolved			
										- ), Headache (3d - Recovered/Resolved			
										- ), Myalgia (3d - Recovered/Resolved			
										- ), Pain in extremity (3d			
										Recovered/Resolved			
EU-EC- 10010329660	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Headache (n/a - Recovered/Resolved - )			

EU-EC- 10010329778	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Acute kidney injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Migraine - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Blood pressure increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Normocytic anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Thrombotic microangiopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010329825	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - ), Pain in extremity (n/a - Not	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Recovered/Not Resolved - ), Vertigo (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010329936	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chorioretinitis (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
										Visual impairment (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010330047	15/10/2021	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Not Recovered/Not Resolved - ), Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010330060	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10010330104	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Presyncope (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving	Intramuscular])		
EU-EC- 10010330428	15/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- ) Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Embolism (n/a - Unknown - Other Medically Important Condition),			
										Heart rate increased (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			

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											Condition), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),				
											Tenderness (n/a - Unknown - Other Medically Important Condition),				
											Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)				
	EU-EC- 10010330434	15/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available		Not Specified	Female	No	Food allergy (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	
											Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Lip swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition),				
											Multiple allergies (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)				
	EU-EC- 10010330470	15/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Female	No	Angina pectoris (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
											Anxiety (n/a - Unknown - ),				
											Blood bicarbonate decreased (n/a - Unknown - ),				
											Carbon dioxide decreased (n/a - Unknown - ),				
											Chest discomfort (n/a - Not Recovered/Not Resolved - ),				
											Chest pain (n/a - Unknown - ),				
											Costochondritis (n/a - Unknown - ),				
											Depressed mood (n/a - Unknown - ),				
											Diarrhoea (n/a - Recovered/Resolved - ),				
											Dysphagia (n/a - Unknown - ),				
											Dyspnoea (n/a - Not Recovered/Not Resolved - ),				
											Fear of death (n/a - Unknown - ),				
											Fibrin D dimer increased (n/a - Recovered/Resolved - ),				
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											Headache (n/a - Unknown - ),			
											Heart rate increased (n/a - Not			
											Recovered/Not Resolved - Other Medically Important			
											Condition),  Hypertension (n/a -			
											Not Recovered/Not Resolved - Other Medically Important			
											Condition),  Hyperventilation (n/a			
											- Unknown - ),  Hypoaesthesia (n/a - Not Recovered/Not			
											Resolved - ), Insomnia (n/a -			
											Unknown - ), Nausea (n/a -			
											Unknown - ), Neck pain (n/a - Not			
											Recovered/Not Resolved - ),			
											Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
											Pain in jaw (n/a - Unknown - ),			
											Palpitations (n/a - Unknown - ),			
											Panic reaction (n/a - Unknown - ),			
											Paraesthesia (n/a - Not Recovered/Not Resolved - ),			
											Product administered at inappropriate site (n/a - Unknown - ),			
											Respiratory rate increased (n/a - Unknown - ),			
											Self-injurious ideation (n/a - Unknown - ),			
											Tachycardia (n/a - Unknown - ),			
	EU-EC-	15/10/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Vomiting (n/a - Unknown - ) Chills (n/a -	COMIRNATY	Not reported	ICSR
	10010330514	13, 10, 2021	Sportaneous	Healthcare	European Economic Area	available	Years	Specified	T IGIC	110	Unknown - ), Diarrhoea (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>100 K</u>
											Unknown - ), Headache (n/a -	n/a])		
											Unknown - ), Malaise (n/a -			
											Unknown - ), Myalgia (n/a -			
											Unknown - ), Nausea (n/a -			
											Unknown - ), Pain (n/a - Unknown			
											- ), Pain in extremity (n/a - Unknown - ),			
											Pyrexia (n/a - Unknown - ),			
											Sluggishness (n/a - Unknown - ),			
											Vomiting (n/a - Unknown - )			
,	EU-EC- 10010330606	15/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Syncope (0d - Recovered/Resolved			
				l	I	I	I	I	I					1 1

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		<u></u>								- Other Medically Important Condition)			
EU-EC- 10010330871	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010331075	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Axillary pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSF
										Flank pain (n/a - Not Recovered/Not Resolved - ),	Intramuscular])		
										Localised oedema (n/a - Not Recovered/Not Resolved - ),			
										Oedema peripheral (n/a - Not Recovered/Not Resolved - ),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site erythema (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site haematoma (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site induration (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site swelling (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010331169	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Muscle spasms (n/a - Unknown - )			
EU-EC- 10010331281	15/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blue toe syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (n/a - Not Recovered/Not Resolved - ),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - ),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010331297	15/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cellulitis (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
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010331305	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Inappropriate schedule of product administration (n/a - Unknown - ),	n/a])		
										Syncope (n/a - Recovered/Resolved - Other Medically			

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										Important Condition),			
										Visual impairment (n/a - Recovered/Resolved			
EU-EC- 10010331411	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010331828	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010331837	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Limb discomfort (6d			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Palpitations (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010332207	15/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010332508	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010332905	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010332978	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Axillary pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Diarrhoea (n/a - Recovered/Resolved - )			
EU-EC- 10010333009	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010333093	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bullous impetigo (n/a - Recovering/Resolving - Other Medically Important Condition),		Not reported	ICSR
										Condition aggravated (n/a - Recovering/Resolving - )			
EU-EC- 10010333693	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010333993	15/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Psychomotor hyperactivity (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10010334440	15/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available		Not Specified	Female	No	Chest pain (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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				Area						-)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010334562	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure abnormal (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Disturbance in attention (n/a - Not Recovered/Not Resolved - Disabling),			
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10010334797	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	IRON [IRON] (C - Iron deficiency - n/a - [n/a - n/a - n/a])	ICSR
										Skin haemorrhage (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010334808	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown - ),  Menstruation irregular (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ATOMOXETINE] (C - Anxiety, Attention deficit hyperactivity disorder, Depression - n/a - [n/a - n/a - n/a]),	ICSR
										Resolved - ),  Vomiting (2d - Recovered/Resolved - )		[MEDROXYPROGESTERONE ACETATE] (C - Menstrual cycle management - n/a - [n/a - 1{DF} - n/a])	
EU-EC- 10010334814	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Peripheral swelling (1d - Recovered/Resolved - ),			
										Vaccination site swelling (1d - Recovered/Resolved -)			
EU-EC- 10010335633	15/10/2021	Spontaneous	Non 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 - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010335638	15/10/2021	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- 10010335665	15/10/2021	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- 10010335826	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (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- 10010335830	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dermatitis bullous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Face oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010335922	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010336151	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (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- 10010336154	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (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	ICSR
EU-EC- 10010336296	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Joint swelling (3d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	15/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Rash (3d - Not Recovered/Not Resolved - ) Amenorrhoea (n/a -	COMIRNATY	Not reported	ICSR
10010336490	13/10/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	i ciliale	INU	Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation -	not reported	<u>ICSK</u>

		<u></u>	<u></u>								Not applicable - [83d - n/a - Intramuscular])		
EU-EC- 10010336552	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving - ), Intermenstrual bleeding (n/a - Recovering/Resolving - ),	COMIRNATY	Not reported	ICSR
										Pain in extremity (n/a - Recovering/Resolving -)			
10010336557	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010336614	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ), Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010336649	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010336688	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Influenza like illness (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010336729	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vulval ulceration (10d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010336754	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erectile dysfunction (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010336788	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site erythema (n/a - Unknown - ), Vaccination site vesicles (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010336826	15/10/2021	Spontaneous	Healthcare Professional	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- 10010336943	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010336979	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),  Oedema (n/a - Not Recovered/Not Resolved - ),  Pain in extremity (n/a - Not Recovered/Not Recovered/Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
10010336994		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Chest discomfort (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), Injection site pain (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010336996	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (9d - Recovered/Resolved - ), Menstrual disorder	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

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										(9d - Recovered/Resolved - ),	<del></del>		
										Pyrexia (9d - Recovered/Resolved - )			
EU-EC- 10010337213	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010337437	15/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site rash (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010337472	15/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010337593	15/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (56d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010337800	15/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (30min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010338213		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menarche (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- 10010338283	15/10/2021	Spontaneous		European Economic Area		12-17 Years	Not Specified	Female	No	Headache (11d - Recovered/Resolved - ), Hypomenorrhoea	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										(n/a - Not Recovered/Not Resolved - ),	1{UF} - I(A])		
										Malaise (11d - Recovered/Resolved - ),			
										Menstruation delayed (11d - Not Recovered/Not Resolved - ),			
										Myalgia (11d - Recovered/Resolved - ), Nausea (5d -			
										Recovered/Resolved			
EU-EC- 10010338318		Spontaneous	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- 10010338640	15/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CYPROTERONE ACETATE, ETHINYLESTRADIOL] (C - Oral contraception - n/a - [n/a - 1{DF} - Oral])	ICSR
										Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Muscle spasms (1d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (1d -			

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										Recovered/Resolved - Other Medically			
EU-EC- 10010338675	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[DESOGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]), [ETHOSUXIMIDE] (C -	ICSR
												Epilepsy - n/a - [n/a - n/a - Oral]),  [IVERMECTIN] (C - Acarodermatitis - n/a - [n/a - n/a - Oral]),	
												[MELATONIN] (C - Insomnia - n/a - [n/a - n/a - Oral]),	
												[QUETIAPINE, QUETIAPINE FUMARATE, QUETIAPINE HEMIFUMARATE] (C - Mental disorder - n/a - [n/a - n/a - Oral]),	
												[SERTRALINE] (C - Anxiety - n/a - [n/a - n/a - Oral]), [ZONISAMIDE] (C -	
												Epilepsy - n/a - [n/a - n/a - Oral])	
EU-EC- 10010338695	15/10/2021	Spontaneous	Healthcare	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 -	Not reported	ICSR
										Hypomenorrhoea (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a])		
EU-EC- 10010338720	15/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardiac murmur (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010338733	15/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adult	Male	No	Chest pain (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
				Area						Caused/Prolonged Hospitalisation), Troponin increased	COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])		
										(n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010339292	15/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010339330	15/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010312091	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (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- 10010313311	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Haemoptysis (3d - Recovered/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 - ),			

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										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),			
										Productive cough (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010313459	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved - ), Vaccination site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Recovered/Resolved - )			
EU-EC- 10010313528	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - ),  Gastrointestinal motility disorder (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	14/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Nausea (n/a - Unknown - ) Lymphadenopathy	COMIRNATY	Not reported	ICSR
10010313530	11,10,2021	Sportaneous	Professional	Economic Area	available	Years	Specified	Haic		(n/a - Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICOIN</u>
EU-EC- 10010313561	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010313565	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - ), Pain in extremity (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010313750	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010313759	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Injection site haemorrhage (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Injection site pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010314013	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010314145	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palmar erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Rash erythematous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Rash pruritic (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010314149	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Mouth haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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										Petechiae (n/a - Unknown - Caused/Prolonged Hospitalisation),	n/a - [n/a - n/a - Intramuscular])		
										Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010314186	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010314573	14/10/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Cough (n/a - Unknown - Other Medically Important Condition),			
										Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - Other Medically Important Condition)			
U-EC- 0010314933	14/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Anaphylactic shock (0d - Recovered/Resolved - Other Medically Important Condition),			
										Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dysphonia (0d - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hypoaesthesia (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hypoaesthesia oral (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hypopnoea (0d - Recovered/Resolved - Other Medically Important Condition),			
										Lacrimation increased (0d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (0d - Recovered/Resolved - Other Medically Important			

										Respiratory rate increased (n/a -			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010315047	14/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (0d - Recovered/Resolved - Life Threatening, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSF</u>
										Dyspnoea (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
										Lip swelling (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition)			
EU-EC- 10010315419	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010315430	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010315559	14/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSF
										Nausea (n/a - Unknown - Other Medically Important Condition),	n/a])		
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010315755	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area		12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010316177	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Recovered/Resolved - ), Rash (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	14/10/2021	Cnontonoous	Hoaltheare	Europoon	Not	12-17	Not	Female	No	Recovered/Resolved - )  Menstruation delayed	COMIDNIATY	NOT AVAILABLE (C. p/s	ICCD
10010316485	14/10/2021	Spontaneous	Professional	European Economic Area	Not available	Years	Not Specified	remale	No	(n/a - Not Recovered/Not Resolved - )	[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- 10010316495	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	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- 10010316508	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a -	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a]	Not reported	ICSR
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (1d - Recovered/Resolved - )			
EU-EC- 10010316512	14/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (2d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Feeling hot (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hypersensitivity (10h			
										Recovered/Resolved - Other Medically			

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											Important Condition),			
											Malaise (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Mass (n/a - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10010316519	14/10/2021	Spontaneous	Professional	Non European Economic Area	Not available		Not Specified	Female	No	Anaphylactic reaction (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
											Blood pressure increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Heart rate increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Peripheral coldness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10010316799	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Impaired work ability (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling),			
											New daily persistent headache (n/a - Not Recovered/Not Resolved - Disabling),			
											Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
											Sleep disorder (n/a - Not Recovered/Not Resolved - Disabling),			
											Social problem (n/a - Not Recovered/Not Resolved - Disabling)			
	EU-EC- 10010317287	14/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10010317653	14/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											Vaccination failure			1

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										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010318003	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Female	No	Paraesthesia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010318132	14/10/2021	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 - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010318156	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (6h - Recovered/Resolved - ), Haematoma (6h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010318211	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (1min - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010319650	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (22d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010319655	14/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Aphonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	.,,-,,		
										Fibromyalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Visual acuity reduced (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010319829	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovered/Resolved - ), Eye pruritus (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - ),			
										Myalgia (n/a - Recovered/Resolved - ), Ocular hyperaemia			
										(n/a - Recovered/Resolved -), Pyrexia (5d -			
										Recovered/Resolved - ), Rash (n/a - Recovered/Resolved			
										- ), Vomiting (n/a - Recovered/Resolved - )			
EU-EC- 10010320284	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Recovered/Not Resolved - ), Vaccination site pain (n/a - Not			
EU-EC- 10010320309	14/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - )  Anti-thyroid antibody (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Aicd						Blood thyroid stimulating hormone increased (n/a - Unknown - Caused/Prolonged Hospitalisation),	Not applicable - [1a - n/a - n/a])		

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									Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
14/10/2021	Spontaneous	Healthcare	Economic	available	Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	DESLORATADINE [DESLORATADINE] (C - n/a - n/a - [n/a - n/a - n/a]),  [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a])	ICSR
14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
									Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - )	Not applicable - [n/a - n/a -	Not reported	<u>ICSR</u>
14/10/2021	Spontaneous	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 -	Not reported	<u>ICSR</u>
14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disturbance in attention (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
									Fatigue (n/a - Not Recovered/Not Resolved - ),	пуају		
									Headache (n/a - Not Recovered/Not Resolved - ),			
									- Not Recovered/Not Resolved - )			
14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
									Recovered/Not Resolved - ),	Intramuscular])		
									Recovered/Not Resolved - )			
14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	Yes	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
4.4/4.0/2024	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Back pain (n/a -	COMIRNATY	Not reported	ICSR
	14/10/2021 14/10/2021 14/10/2021 14/10/2021 14/10/2021 14/10/2021	14/10/2021         Spontaneous           14/10/2021         Spontaneous	14/10/2021 Spontaneous Non Healthcare Professional 14/10/2021 Spontaneous Non Healthcare Professional 14/10/2021 Spontaneous Non Healthcare Professional 14/10/2021 Spontaneous Healthcare Professional	14/10/2021       Spontaneous Professional P	14/10/2021 Spontaneous Non Healthcare Professional Area  14/10/2021 Spontaneous Healthcare Professional Area	14/10/2021 Spontaneous Non Healthcare Professional Realthcare Reconomic Professional Realthcare Reconomic Realthcare Professional Realthcare Reconomic Realthcare Professional Realthcare Reconomic Reconomic Reconomic Realthcare Reconomic Reconomic Realthcare Reconomic Reconomic Realthcare Reconomic Reconomic Realthcare Reconomic R	14/10/2021   Spontaneous   Non Healthcare   European Area   Not Wears   Specified	14/10/2021 Spontaneous Non Healthcare Professional Area Professional Professional Professional Professional Professional Professional Prof	14/10/2021 Spontaneous Non Healthcare European Not Area No Professional Area No Professional Area No Professional Non Healthcare European Not Area Not Non Healthcare European Not Non Non Healthcare European Not Non Non Not Non Non Healthcare European Not European Not Non Non Non Non Healthcare European Not Europe	14/10/2021   Sportaneous   Healthcare   European   Not Professional   Area   Not Professional   Not Profes	14/10/2021   Spontaneous   Non   Healthcare   Constitution   Professional   Non-   Constitution   Professional   Non-   Constitution   Professional   Non-   Constitution   No	Mail

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										Recovering/Resolving - )			
:U-EC- 0010321645	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (7d - Recovered/Resolved -), Vertigo (7d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSF</u>
EU-EC- 10010321647	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- )   Influenza like illness   (n/a -   Recovering/Resolving  - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10010321684	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site pain (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010321923	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Thrombocytopenic purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10010321952	14/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disease recurrence (7d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICS
										Immune thrombocytopenia (7d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010321960	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dermatitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSI
										Skin lesion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010322017	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - ), Body temperature increased (2d - Recovered/Resolved - ), Chills (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Cough (n/a - Not Recovered/Not Resolved - ), Ear discomfort (n/a -			
										Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Recovering/Resolving -), Musculoskeletal			
										chest pain (2d - Recovered/Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ), Nausea (2d -			
EU-EC-	14/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Resolved - ) Fatigue (n/a -	COMIRNATY	Not reported	ICS
10010322019	1-1/ 10/ 2UZI	эропапеоus	Healthcare Professional	Economic	available	Years	Specified	i cinale	INU	Patigue (n/a - Unknown - ), Premenstrual dysphoric disorder (2mo - Recovered/Resolved	COMINNAIY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	пыс геропей	100
EU-EC- 10010322034	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Device expulsion (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	SPIRAAL (SPIRAALTJE, INTRAUTERINE DEVICE, IUD, INTRAUTERINE CONTRACEPTIVE DEVICE)	ICSF

										Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ),		[NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),			
U-EC- 0010322067	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - ) Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [34d -	Not reported	ICSR
U-EC- 0010322140	14/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	2{DF} - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	LATUDA [LURASIDONE, LURASIDONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
												[ETHINYLESTRADIOL, NORETHISTERONE, NORETHISTERONE ACETATE, ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[MAGNESIUM OXIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[RIBOFLAVIN] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
U-EC- 0010322236	14/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
U-EC- 0010322401	14/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Multisystem inflammatory syndrome in children (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically			

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EU-EC- 10010322429	14/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Interchange of vaccine products (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]),	Not reported	ICSR
											SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID- 19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])		
EU-EC- 10010323325	14/10/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area			ľ			Nausea (1d - Recovered/Resolved - ),	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010323344	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (5d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a -	Not reported	ICSR
			roressional	Area						Headache (5d - Not Recovered/Not Resolved - ),	n/a - n/a])		
511 FO	14/40/2021			N		12.17				Malaise (5d - Not Recovered/Not Resolved - )	TO TRANSPORT		1000
EU-EC- 10010324549	14/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ageusia (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
										Anosmia (n/a - Unknown - Other Medically Important Condition),			
										Erectile dysfunction (n/a - Unknown - Other Medically Important Condition),			
										Feeling cold (n/a - Unknown - Other Medically Important Condition),			
										Nasopharyngitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10010324621	14/10/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Condition) Cardiovascular disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a -	Not reported	ICSR
EU-EC- 10010326001	14/10/2021	Spontaneous		Area Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown - )  COVID-19 (n/a - Unknown - Other Medically Important Condition),	n/a - [n/a - n/a - n/a])  TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Aicu						Cough (n/a -	n/a])		
										Unknown - ), Drug ineffective (n/a - Unknown - Other Medically Important			
										Condition), Feeling cold (n/a - Unknown - ),			
EU-EC-	14/10/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Malaise (n/a - Unknown - ) Fatigue (0d -	COMIRNATY	Not reported	ICSR
10010326655			Healthcare Professional	Economic Area	available	Years				Unknown - ), Influenza (0d - Unknown - ),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Influenza (2d - Recovered/Resolved - ),			
										Injection site pain (5d - Recovered/Resolved -),			
										Malaise (0d - Recovered/Resolved - ),			
										Nasal congestion (2d			
tnoulldor =		 a.eu/analv	tion/nov: d							Recovered/Resolved	l		38/6

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										- ), Nausea (0d - Recovered/Resolved - ),			
										Oropharyngeal pain (0d - Unknown - )			
EU-EC- 10010327046	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy (2d -	ilya - ilyajj		
										Recovered/Resolved - ),			
										Pain in extremity (2d			
										Recovered/Resolved - ),			
										Somnolence (2d - Recovered/Resolved			
EU-EC-	14/10/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Myocarditis (n/a -	COMIRNATY	Not reported	ICSR
10010327095		·		Economic Area	available	Years				Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	
EU-EC- 10010327107	14/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Swelling face (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						ŕ	Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010327495	14/10/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Migraine (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
				Area						Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - n/a])		
EU-EC- 10010327513	14/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (47min - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Bronchostenosis	n/a])		
										(47min - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (47min - Recovered/Resolved - ),			
										Presyncope (47min - Recovered/Resolved - )			
EU-EC- 10010327617	14/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (66d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Vomiting (66d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010327699	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICSR
										Limb discomfort (n/a - Unknown - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a -		
										Microembolism (n/a - Unknown - Life Threatening),	2{DF} - n/a])		
										Vaccination site pain (n/a - Unknown - Life Threatening)			
EU-EC- 10010328243	14/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Tremor (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010328325	14/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cold sweat (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Diarrhoea (0d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved			
										, , , , , , , , , , , , , , , , , , , ,			

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										- Other Medically Important Condition)			
EU-EC- 10010328734	14/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010328999	14/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved - Other Medically Important Condition),			
										Mental fatigue (2d - Recovered/Resolved - Other Medically Important Condition),			
										Somnolence (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010300017	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - ),	COVID-19 immunisation -	SPIRAAL (SPIRAALTJE, INTRAUTERINE DEVICE, IUD, INTRAUTERINE	ICSR
										Injection site inflammation (n/a - Recovered/Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])	CONTRACEPTIVE DEVICE) [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Injection site pain (n/a - Recovered/Resolved - ),			
										Injection site swelling (n/a - Recovered/Resolved - ),			
										Injection site warmth (n/a - Recovered/Resolved - ),			
										Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010301174	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ecchymosis (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - ),	1{DF} - Intramuscular])		
										Nausea (n/a - Recovering/Resolving - ),			
										Paraesthesia (n/a - Recovering/Resolving - )			
EU-EC- 10010301257	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (6d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	<u>ICSR</u>
										Pyrexia (6d - Recovered/Resolved - )	Intramuscular])		
EU-EC- 10010301259	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010301331	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Headache (n/a - Unknown - ),	Not applicable - [n/a - n/a - Intramuscular])		
										Pyrexia (n/a - Unknown - ),			
EU-EC-	13/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Vaccination site pain (n/a - Unknown - ) Hyperventilation (n/a	COMIDNATY	Not reported	ICSR
10010301365	13/10/2021	Sportaneous	Professional		available	Years	Specified	remale		- Recovering/Resolving	[TOZINAMERAN] (S -	Not reported	ICOK
										Injection site pain (n/a - Recovering/Resolving -),	- Intramuscular])		
										Myalgia (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving			

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										- ), Tachycardia (n/a - Recovering/Resolving			
EU-EC- 10010301492	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - ), Chest pain (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
										Pyrexia (n/a - Recovered/Resolved			
EU-EC- 10010301520	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Injection site pain (n/a - Recovered/Resolved - ),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Somnolence (n/a - Recovered/Resolved - )			
EU-EC- 10010301599	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010301711	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Paraesthesia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010301771	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ), Urticaria (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC-	13/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Recovering/Resolving - ) Diarrhoea (n/a - Not	COMIRNATY	Not reported	ICSR
10010301804			Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Salivary hypersecretion (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 14DF} - Intramuscular])		
										Resolved - ),  Tachycardia (n/a - Not Recovered/Not Resolved - ),  Vomiting (n/a - Not			
EU-EC-	12/10/2021	Spontaneous	Hoalthcaro	European	Not	12-17	Not	Female	No	Recovered/Not Resolved - ) Myocarditis (n/a -	COMIRNATY	Not reported	ICSR
10010301810	13/10/2021	эропсанеоиз	Professional	Economic Area	available	Years	Specified	remaie	No	Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	100
EU-EC- 10010301815	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010301835	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovering/Resolving - ), Peripheral swelling (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010302309	13/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Grip strength decreased (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscular weakness	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
	10/12/2013									(520min - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010302382	13/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Inappropriate schedule of product administration (n/a - Unknown - ),			

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										Inflammation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Inner ear inflammation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Optic neuritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010302423	13/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Apraxia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Blepharospasm (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010302695	13/10/2021	Spontaneous		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 - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010302705	13/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010303682	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (24h - Recovered/Resolved - ), Rash erythematous	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										(24h - Recovered/Resolved - ), Skin warm (24h -			
										Recovered/Resolved - ), Urticaria (24h - Recovered/Resolved			
EU-EC- 10010303928	13/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ) Alopecia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Alopecia areata (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - ),			
										Skin disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010303974	13/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010304222	13/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Presyncope (n/a -   Recovering/Resolving  - Other Medically   Important Condition)			
EU-EC- 10010304700	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICS
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- .0010304854	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Eye pain (3d - Recovered/Resolved - ),	1{DF} - n/a])		
										Eye swelling (3d - Recovered/Resolved - ),			
										Headache (3d - Recovered/Resolved - ),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),			
										Malaise (3d - Recovered/Resolved - ),			
										Nausea (3d - Recovered/Resolved - ),			
										Pyrexia (3d - Recovered/Resolved - )			
U-EC- 0010305005	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
U-EC- 0010305010	13/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Spinal pain (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 25mg - n/a])	
										Not Recovered/Not Resolved - )	(NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
U-EC- .0010305029	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Localised oedema (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
										Paraesthesia (n/a - Unknown - )	Unknown - [n/a3mL - Intramuscular])		
:U-EC- 0010305062	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
										Rash erythematous (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a])		
EU-EC- .0010305383	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LORATADINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 10010305823	13/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	n/a])		
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Paraesthesia (n/a - Unknown - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved			

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										- Other Medically Important Condition)			
EU-EC- 10010305845	13/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Oropharyngeal discomfort (n/a - Recovered/Resolved - ),			
										Upper respiratory tract inflammation (n/a - Recovered/Resolved -)			
EU-EC- 10010305870	13/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysphoria (510min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (510min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Restlessness (510min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
				_						Tachycardia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010305916	13/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Recovered/Not Resolved - ),	Intramuscular])		
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010305963	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010306362	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]),	Not reported	ICSR
										Intermenstrual bleeding (n/a - Recovered/Resolved - )	[NOT AVAILABLE] (S - Product used for unknown indication - Drug withdrawn - [n/a - n/a - n/a])		
EU-EC- 10010306370	13/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness postural (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CEFDINIR] (C - n/a - n/a - [n/a - n/a - n/a]), [CEFOTAXIME SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Feeling cold (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Inappropriate schedule of product administration (n/a - Unknown - ),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Peripheral coldness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010306442	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Haemangioma of spleen (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Hospitalisation),			
										Influenza like illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010307053	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema multiforme (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010307247	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010307349	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Local reaction (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010307582	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - ) Dysmenorrhoea (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Headache (n/a - Recovered/Resolved - ), Heavy menstrual	1{DF} - n/a])		
										bleeding (n/a - Recovered/Resolved - ), Presyncope (n/a -			
										Recovered/Resolved - )			
10010307617		Spontaneous	Professional	European Economic Area	Not available	Years	Adolescent		No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010307686	13/10/2021				Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	[ETHINYLESTRADIOL, NORGESTIMATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Malaise (n/a - Recovered/Resolved - ), Pelvic pain (n/a -			
										Recovered/Resolved			
EU-EC- 10010307711	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010307736	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										Recovered/Not Resolved - ), Headache (n/a - Recovered/Resolved			
										- ), Hyperthermia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010307786	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tooth infection (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10010307792	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (n/a - Recovered/Resolved - ), Anosmia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Immunisation reaction (n/a - Recovered/Resolved - ),			

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										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010308052	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010308237	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010308304	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site papule (1d - Recovered/Resolved - ), Injection site pruritus (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010308341	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ),  Dyspnoea (n/a - Recovered/Resolved - ),  Headache (n/a - Not Recovered/Not Resolved - ),  Nausea (n/a - Recovering/Resolving - ),  Pyrexia (n/a - Recovering/Resolving - ),  Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010308564	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Face oedema (n/a - Recovering/Resolving - ), Lymphadenopathy (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010308701	13/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010308702	13/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abscess oral (n/a - Recovering/Resolving - Other Medically Important Condition),  Bronchial secretion retention (n/a - Recovering/Resolving - Other Medically Important Condition),  Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),  Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),  Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition),  Increased bronchial secretion (n/a - Unknown - Other Medically Important Condition),  Increased bronchial secretion (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]),  SIALANAR [GLYCOPYRRONIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]),  [BACLOFEN] (C - n/a - n/a - [n/a - n/a - n/a]),  [CLONAZEPAM] (C - Epilepsy - n/a - [n/a - n/a - n/a]),  [DOMPERIDONE, DOMPERIDONE, DOMPERIDONE MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]),  [LANSOPRAZOLE] (C - n/a - n/a]),  [LEVOTHYROXINE, LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a - n/a - n/a]),  [MAGNESIUM ALGINATE, SODIUM ALGINATE] (C - n/a - n/a - [n/a - n/a - [n/a - n/a]),	

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										secretion (n/a - Unknown - Other Medically Important Condition),		[POTASSIUM CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Jaw clicking (n/a - Recovered/Resolved - Other Medically Important Condition),		[SALINE, SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TOPIRAMATE] (C -	
										Menstrual disorder (n/a - Unknown - Other Medically Important Condition),		Epilepsy - n/a - [n/a - n/a - n/a])	
										Muscle spasms (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nervous system disorder (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tongue abscess (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010308718	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (3wk - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010309216	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
										Sickle cell anaemia with crisis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
10010309249	13/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Specified	Female	No	- Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010309286	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (30min - Recovered/Resolved - ), Fatigue (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular - More in ICSR])	Not reported	ICSR
										Puncture site pain (48h - Recovered/Resolved - ), Pyrexia (6h - Recovered/Resolved			
EU-EC-	13/10/2021	Spontaneous		European	Not	12-17	Not	Female	No	- ) Amenorrhoea (n/a -	COMIRNATY	Not reported	ICSR
10010309374			Healthcare Professional	Economic Area	available	Years	Specified			Unknown - )	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010309481		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Vomiting (3d - Recovering/Resolving - )	COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010309584	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation normal (n/a - Recovered/Resolved - ), Puberty (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010309613	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eczema (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010309769	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Autoimmune neutropenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 2{DF} - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - Dose increased - [n/a - n/a - Oral])	ICSR

											Condition aggravated (n/a - Recovered/Resolved - Caused/Prolonged			
											Hospitalisation), Immune thrombocytopenia			
											(n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-1	EC- 10309774	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1d - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Dyspnoea (1d - Unknown - Other Medically Important Condition),			
											Fatigue (1d - Unknown - Other Medically Important Condition),			
											Headache (1d - Unknown - Other Medically Important Condition),			
											Photophobia (1d - Unknown - Other Medically Important Condition),			
											Somnolence (1d - Unknown - Other Medically Important Condition),			
											Syncope (1d - Unknown - Other Medically Important Condition),			
											Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition)			
EU-1	EC- 10309866	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adult	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-1	EC- 10309900	13/10/2021	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 applicable - [1d - n/a -	Not reported	ICSR
											Language disorder (n/a - Recovering/Resolving - Other Medically Important Condition)	n/aj)		
EU-I	EC- 10309904	13/10/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving		Not reported	ICSR
				Professional	Economic Area						- Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
											Ear pain (148h - Recovered/Resolved - Other Medically Important Condition),			
											White blood cell count increased (n/a - Unknown - )			
EU-I 100	EC- 10309907	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (12d - Unknown - ), Menstruation delayed	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
											(12d - Recovered/Resolved - )	1{DF} - Intramuscular])		
EU-1	EC- 10309919	13/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-1	EC- 10309993	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Depression (n/a - Not Recovered/Not Resolved - ),	n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
F11	FC.	12/10/222	Co. and	New	F	N-4	12.47	A	M-I	NI.	Recovered/Not Resolved - )	1{DF} - Intramuscular])	ECI ODAZAMI (O	Icca
EU-1	10310046	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	мае	No	Influenza like illness (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[CLOBAZAM] (C - n/a - n/a - ), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - n/a - n/a - ),	ICSR
													[VALPROIC ACID, SODIUM	

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U-EC- 0010310078	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (1d - Recovered/Resolved - ), Lymphadenopathy (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICS
										- ), Pyrexia (8h - Recovered/Resolved - )			
U-EC- 0010310192	13/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved - ), Blood pressure	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										increased (n/a - Recovered/Resolved - ), Convulsions local			
										(n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate increased (n/a - Recovered/Resolved - ),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - ),			
										Presyncope (n/a - Recovered/Resolved - ),			
EU-EC-	12/10/2021	Spontaneous	Non	Europoan	Not	12-17	Not	Fomalo	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition) Hypomenorrhoea	COMIRNATY	Not reported	ICC
.0010310254	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	available	Years	Specified	Female	INO	(n/a - Not Recovered/Not Resolved - ),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC-	13/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - ) Headache (n/a - Not	COMIRNATY	Not reported	ICS
0010310287	13/10/2021	Spontaneous	Healthcare	Economic Area	available	Years	Specified	remale	INO	Recovered/Not Resolved - ), Injection site pain	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	100
										(n/a - Recovering/Resolving - ), Malaise (n/a - Not			
										Recovered/Not Resolved - ), Nausea (n/a - Recovering/Resolving			
										- ), Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- .0010310383	13/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- .0010310443	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - ), Influenza like illness (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Pyrexia (n/a - Unknown - )			
EU-EC- 0010310524	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (0d - 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	12/10/2024	Coorter	Non	Europe	Not	12.17	Not	Mala	Ne	Vomiting (13h - Recovered/Resolved - Other Medically Important Condition)	COMTONIATY	Not report-	TOO
EU-EC- .0010310531	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS

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										Diarrhoea (n/a - Recovering/Resolving - ),	Not applicable - [n/a - n/a - n/a])		
										Loss of personal independence in daily activities (n/a - Recovering/Resolving - ),			
										Rash (3d - Recovered/Resolved - )			
EU-EC- 10010310819	13/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Ventricular extrasystoles (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010310820	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Unknown - Other Medically Important Condition),	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
										Haematoma (n/a - Unknown - Other Medically Important Condition),	1(01) 11/41)		
										Haematuria (n/a - Unknown - Other Medically Important Condition),			
										Immune thrombocytopenia (n/a - Not Recovered/Not			
										Resolved - Other Medically Important Condition),			
										Mucosal haemorrhage (n/a - Unknown - Other Medically Important Condition),			
										Petechiae (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010310859	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
			Froiessional	Alea						COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	Not applicable - [n/a - n/a - n/a])		
										Cyanosis (n/a - Recovered/Resolved - Life Threatening),			
										Dizziness (n/a - Recovered/Resolved - Life Threatening),			
										Dyspnoea exertional (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Exercise tolerance decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate increased (n/a - Recovered/Resolved - Life Threatening),			
										Hypotension (n/a - Recovered/Resolved - Life Threatening),			
										Nasopharyngitis (n/a			
										Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Life Threatening),			
tns://dan.ei		a outanche	tias/saw.d							Pain in extremity (n/a -			50/6

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Page															
Due												Recovered/Resolved			
Button												Recovered/Resolved - Other Medically Important			
United   U												Rash erythematous (n/a - Recovered/Resolved			
B-EC   13/19/2021   Sportaneza   Perfect   P												Urticaria (n/a -			
13/13/2021   Dordantess   Water   Dordantess   Water   Dordantess   Water   Dordantess   Water   Wat												Vomiting (n/a -			
Residence   Processor   Proc	EU-EC-		13/10/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	- Life Threatening) Diarrhoea (n/a - Not	COMIRNATY	Not reported	ICSR
Bit	100103	11160					available	Years	Specified				COVID-19 immunisation -		
												Recovered/Not			
Processor   Proc												Recovered/Not Resolved - )			
EU-EC   13/10/2021   Sportaneous   Peathtrace   Aces   More   M			13/10/2021	Spontaneous	Healthcare	Economic				Female	No	Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
Page			13/10/2021	Spontaneous					Adolescent	Female	No	Abdominal pain (n/a	COMIRNATY	Not reported	ICSR
ELEC-   13/10/2021   Spontaneous   Healthrane   European   Not   12-17   Addressent   Male   No   Name   Recovering/Resolving   Press (n/s - Name   Professional   Professio						Area							Not applicable - [1d - n/a -		
ELFEC   13/10/2021   Spontaneous   Healthcare   European   Not   12-17   Addescent   Male   No   Not   Major   COMIRMATY   C												Recovering/Resolving	Indumuscular I)		
EU-EC_   13/10/2021   Spontaneous   Healthcare   European   Professional Common   Avea   Male   No   Recovering Resolving   COMINANTY   COMINANTY   Common												Recovering/Resolving			
EU-EC-   101/10/2021   Spontaneous Non Healthcare Professional			13/10/2021	Spontaneous		Economic			Adolescent	Male	No	Nausea (n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC-   13/10/2021   Spontaneous   Non   Healthcare   Professional   Area   Not   Pears   Specified   Professional   Not   Pears   Specified   Pears   Spec			13/10/2021	Spontaneous					Adolescent	Male	No	Limb discomfort (n/a	COMIRNATY		ICSR
EU-EC- 10010311463   13/10/2021   Spontaneous   Non Healthcare   Economic Professional Area   12-17   Not Not Recovering/Resolving   -),   Headsche (n/a - R					Professional								COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC- 10010311463 Professional Recovering/Resolving - Pyrexia (n/a - Recovered/Resolved - Pyrexia (n/a - Recovered/Resolved - Pyrexia (n/a - Recovering/Resolving - Pyrexia (n/a - Pyrexia (n/a - Pyrexia (n/a - Pyrexia (n/a												Recovering/Resolving	1,41,		
EU-EC-   13/10/2021   Spontaneous   Non   Healthcare   Professional   Not   Leuropean   Not   Leurop												Recovering/Resolving			
EU-EC- 10010311967   13/10/2021   Spontaneous Ron Healthcare Professional   European Healthcare Professional   Area   Not reported   Not available   Vears   Not reported   Not reported   Not available   Vears   Not Recovered/Resolved - ),   Common Recoverence Recovered/Resolved - ),   Lymphadenopathy (n/a - Recoverng/Resolving - ),   Lymphadenopathy (n/a - Not applicable - [n/a - n/a - [n/a - n/a - n/a - [n/a - n/a - n/a - n/a - [n/a - n/a -												Recovering/Resolving			
EU-EC- 10010311967   Topic			13/10/2021	Spontaneous	Healthcare	Economic				Male	No	Chills (0d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC-   13/10/2021   Spontaneous   Non   Healthcare   Professional   Non   Area   Specified   Female   Not   Recovered/Resolving   -),   Headache (n/a - Recovered/Resolving   -),   Headache (n/a												Recovered/Resolved			
EU-EC- 1010311967  EU-EC- 10010311967  EU-EC- 10010311974  EU-EC-												(n/a - Recovering/Resolving			
EU-EC-1010311967    Spontaneous   Non Healthcare   Professional   Not Available   Not Recovered/Resolved   No												(n/a - Recovering/Resolving			
EU-EC- 1010311974    Spontaneous   Not applicable - [n/a - n/a - n			13/10/2021	Spontaneous	Healthcare	Economic				Female	No	Arthralgia (n/a - Recovered/Resolved	[TOZINAMERAN] (S -	PROLONGED-RELEASE	ICSR
EU-EC- 10010311974					rrotessional	Area						Fatigue (7d - Recovered/Resolved	Not applicable - [n/a -	- n/a - n/a - [n/a - n/a -	
EU-EC- 10010311974												Headache (n/a - Recovering/Resolving			
10010311974 Healthcare Professional Area Feature Professional Area Professional Area Feature Pro												Malaise (4d - Recovered/Resolved			
			13/10/2021	Spontaneous	Healthcare	Economic				Female	No	Chest discomfort (n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

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											Chest pain (n/a - Recovering/Resolving - ),			
											Fatigue (n/a - Recovering/Resolving - ),			
											Headache (n/a - Not Recovered/Not			
	EU-EC- 10010312060	13/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Resolved - ) Headache (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	ANTIHISTAMINICUM [NOT AVAILABLE] (C - n/a - n/a -	ICSR
				Professional	Area						Injection site	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[n/a - n/a - n/a])	
											Recovered/Resolved - ),			
											Injection site pain (1d - Recovered/Resolved -),			
											Injection site swelling (1d -			
											Recovered/Resolved - ), Polymenorrhoea (n/a			
	EU-EC- 10010312212	13/10/2021	Spontaneous	Non Healthcare	European	Not available	12-17 Years	Adolescent	Female	No	- Unknown - ) Abdominal pain (n/a	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
	10010312212				Economic Area	avallable	rears				Recovering/Resolving ),	COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])		
											Nausea (n/a - Recovering/Resolving - )			
	EU-EC- 10010312224	13/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (15min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	<u>ICSR</u>
	EU-EC- 10010312345	13/10/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Deafness (n/a - Unknown - Other	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
				Professional	Economic Area						Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
											Deafness bilateral (n/a - Not Recovered/Not Resolved - Other			
											Medically Important Condition),			
											Dysphagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Migraine (2d - Recovered/Resolved - Other Medically Important Condition),			
											Nasal dryness (n/a - Not Recovered/Not			
											Resolved - Other Medically Important Condition),			
											Oropharyngeal pain (n/a - Not Recovered/Not			
											Resolved - Other Medically Important Condition),			
											Tension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Ulcer (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10010312398	13/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
	EU-EC-	13/10/2024	Sporton	Non	European	Not	12 17	Not	Fomala	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIDNATY	Not reported	ICCD
	EU-EC- 10010312463	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
											Headache (2d - Recovered/Resolved - ),	1{DF} - n/a])		
											Malaise (2d -			

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										Recovered/Resolved			
										Myalgia (2d - Recovered/Resolved - ),			
										Nausea (2d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10010312464	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved - ),	1{DF} - n/a])		
										Hyperpyrexia (n/a - Recovering/Resolving - ),			
EU-EC-	12/10/2021	Spontaneous	Hoolthoore	European	Not	12.17	Adolescent	Mala	No	Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY	AERIUS 5 MG FILM-	ICCD
10010312495	13/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (3d - Recovered/Resolved - ), Vaccination site	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	COATED TABLET  [DESLORATADINE] (C - Rhinitis allergic - Not applicable - [n/a - n/a -	<u>ICSR</u>
										lymphadenopathy (n/a -	-	Oral]), [DEXCHLORPHENIRAMINE	
										Recovering/Resolving - )		MALEATE] (C - Hypersensitivity - Not applicable - [n/a - n/a - Oral]),	
												[MITE ALLERGEN EXTRACT] (C - Rhinitis allergic - Not applicable - [n/a - n/a - Subcutaneous]),	
												[TERBUTALINE SULFATE] (C - Asthma - Not applicable - [n/a - n/a - Other])	
EU-EC- 10010312528	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010312540	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain upper (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL	Not reported	ICSR
										Asthenia (n/a - Recovering/Resolving - ),	- Intramuscular])		
										Pyrexia (3d - Recovered/Resolved - ),			
										Vomiting (3d - Recovered/Resolved - )			
EU-EC- 10010312549	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pityriasis rosea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010312559	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Formication (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010312694	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Vomiting (1d - Recovered/Resolved - )	1{DF} - Intramuscular])		
EU-EC- 10010312696	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site reaction (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010312731	13/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10010312734	13/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Rash (1d - Recovered/Resolved	n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						-)	COVID-19 immunisation - Not applicable - [15d - n/a - Intramuscular])		
EU-EC- 10010312749	13/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood immunoglobulin E increased (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
										Medically Important	n/a])		

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										Condition),  Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Mite allergy (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010313016	13/10/2021	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 reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - ),			
										Rhinorrhoea (n/a - Recovering/Resolving - )			
EU-EC- 10010313251	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (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])	ICSR
EU-EC- 10010313275	13/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Malaise (1d - Recovered/Resolved - ),	1{DF} - n/a])		
										Palpitations (4h - Recovered/Resolved - )			
EU-EC- 10010286900	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Injection site pain (3d - Recovered/Resolved	1{DF} - n/a]), [MEDROXYPROGESTERONE		
										- ), Myalgia (3d - Recovered/Resolved - )	ACETATE] (S - n/a - Dose not changed - [n/a - n/a - n/a])		
EU-EC- 10010287103	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - ),	Not applicable - [n/a - 1{DF} - Intramuscular])		
										Paraesthesia (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010287258	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010287334	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other		Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			

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Building								Recovered/Not Resolved - Other Medically Important			
Busic								Recovered/Not Resolved - Other Medically Important			
Building								Not Recovered/Not Resolved - Other Medically Important			
Professional Pro								Recovered/Not Resolved - Other Medically Important			
Exercised   Part   Pa		12/10/2021	Spontaneous	Economic		Male	No	immunisation (27d - Recovered/Resolved - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug -	Not reported	ICSR
ELECTION   12/19/2021   Sprintaneous   Healthcare   Emperor   Mode   Property   Mo		12/10/2021	Spontaneous	Economic		Female	No	Myalgia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
Building		12/10/2021	Spontaneous	Economic		Male	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
No.   No.   No.   Recovered Note   No.								Recovered/Not			
Professional Economic Area  Professional Professional Recovered Prof								Not Recovered/Not			
Page		12/10/2021	Spontaneous	Economic		Male	No	Recovered/Not	[TOZINAMERAN] (S - COVID-19 prophylaxis - Not	Not reported	<u>ICSR</u>
EU-EC- 1010287416 Part								Not Recovered/Not			
EU-EC- 1010287415  12/10/2021 Spontaneous Healthcare European Not Read-Recovered/Not Recovered/Not R								Not Recovered/Not			
Professional Economic Area available Professional Economic Area Economic Area (VI) - Chest pain (N/a - Not Recovered/Not Resolved - Caused/Professional Economic Area (VI) - Not Recovered/Not Resolved - Caused/Professional Economic Area (VI) - Not Recovered/Not Resolved - Caused/Professional Economic Area (VI) - Not Recovered/Not Resolved - Caused/Professional Economic Area (VI) - Not Recovered/Not Resolved - Caused/Professional Economic Area (VI) - Not Recovered/Not Resolved - Caused/Professional Economic Area (VI) - Not Recovered/Not								Recovered/Not			
Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Malaise (n/a - Not Recovered/Not Resolved) Caused/Prolonged Caused/Prolonged Hospitalisation),  Myocarditis (n/a - Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Myocarditis (n/a - Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Nausea (n/a - Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Pyrexia (n/a - Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Pyrexia (n/a - Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Supraventricular tachycardia (n/a - Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Toponini Tin Creased (n/a - Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Toponini Tin Creased (n/a - Not Recovered/Not Recovered/Not Resolved) - Caused/Prolonged Hospitalisation),  Toponini Tin Creased (n/a - Not Recovered/Not Recover				Economic		Male	No	Recovered/Not Resolved - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Preval (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Resolved - Caused/Prolonged Hospitalisation),  Supraventricular tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Resolved - Caused/Prolonged Hospitalisation)								Recovered/Not Resolved - Caused/Prolonged			
Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Supraventricular tachycardia (n/a - Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Toponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Toponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)  EU-EC- 12/10/2021 Spontaneous Healthcare European Not 12-17 Not Male No Pericardial effusion COMIRNATY Not reported ICSR								Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Supraventricular tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)  EU-EC- 12/10/2021 Spontaneous Healthcare European Not 12-17 Not Male No Pericardial effusion COMIRNATY Not reported ICSR								Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Supraventricular tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)  EU-EC- 12/10/2021 Spontaneous Healthcare European Not 12-17 Not Male No Pericardial effusion COMIRNATY Not reported ICSR								Recovered/Not Resolved - Caused/Prolonged			
tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)  EU-EC- 12/10/2021 Spontaneous Healthcare European Not 12-17 Not Male No Pericardial effusion COMIRNATY Not reported ICSR								Recovered/Not Resolved - Caused/Prolonged			
Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)  EU-EC- 12/10/2021 Spontaneous Healthcare European Not 12-17 Not Male No Pericardial effusion COMIRNATY Not reported ICSR								tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 12/10/2021 Spontaneous Healthcare European Not 12-17 Not Male No Pericardial effusion COMIRNATY Not reported ICSR								Troponin T increased (n/a - Not Recovered/Not Resolved -			
10010287468 Professional Economic available Years Specified (n/a - Unknown - ), [TOZINAMERAN] (S -	1							(Caused/Prolonged			

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				Area						Tachycardia (n/a - Unknown - )	COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
EU-EC- 10010287544	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Injection site pain (2d - Recovered/Resolved -),	11/a - [11/a - 11/a - 11/a])		
										Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10010287584	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Cough (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pericardial effusion (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010287858	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ear pain (6d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF
										Headache (6d - Recovered/Resolved - ),	n/a - [n/a3mL - Intramuscular])		
										Oropharyngeal pain (6d - Recovered/Resolved - ),			
										Pyrexia (6d - Recovered/Resolved - )			
EU-EC- 10010287900	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (37d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSF
										Pyrexia (37d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Tachycardia (37d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010288015	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010288892	12/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaginal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		[DESOGESTREL, ETHINYLESTRADIOL] (C - Contraception - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010289128	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (1h - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]),	Not reported	ICSF
											IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (S - Local reaction - Unknown - [n/a - 300mg - Oral])		
EU-EC- 10010289314	12/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperthermia (n/a - Unknown - ), Lymphocyte count decreased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Unknown - ), Malaise (n/a - Not			
										Recovered/Not			

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										Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010289556	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	C-reactive protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DESOGESTREL, ETHINYLESTRADIOL] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
										Epistaxis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Haematoma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Immune thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Petechiae (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010290077	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
										Malaise (n/a - Unknown - ), Nausea (n/a -	Not applicable - [n/a - 1{DF} - Intramuscular])		
										Unknown - ), Vomiting (n/a -			
EU-EC-	12/10/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Unknown - ) Chest pain (n/a - Not		Not reported	<u>ICSR</u>
10010290241			Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved - ), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010290270	12/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Syncope (8d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010290340	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Unknown - )		Not reported	ICSR
EU-EC- 10010290364	12/10/2021	Spontaneous	Non Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Nausea (n/a - Recovering/Resolving - ), Rhinitis (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (n/a - Recovering/Resolving - )			
EU-EC- 10010290377	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Myalgia (n/a - Recovering/Resolving - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving - )			
EU-EC- 10010290379	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (n/a - Recovering/Resolving			

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										- Caused/Prolonged Hospitalisation),			
										Epilepsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Feeling cold (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Feeling of body temperature change (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Swelling face (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
	EU-EC- 10010290468	12/10/2021	Spontaneous	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blindness transient (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Blindness unilateral (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10010290554	12/10/2021	Spontaneous	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fibrin D dimer increased (3d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Haematoma (n/a - Unknown - )			
	EU-EC- 10010291026	12/10/2021	Spontaneous	European Economic Area	Not available		Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ),	COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Diarrhoea (1d - Recovered/Resolved - ),	1{DF} - n/a])		
										Headache (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Nausea (1d - Recovered/Resolved - )			
	EU-EC- 10010291027	12/10/2021	Spontaneous	European Economic	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (3mo - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	CERVARIX SUSPENSION FOR INJECTION [HUMAN	<u>ICSR</u>

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			Professional							Resolved - ), Injection site pain (1d - Recovered/Resolved - )	Not applicable - [n/a - 1{DF} - n/a])	PAPILLOMAVIRUS TYPE 16 L1 PROTEIN, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN, MONOPHOSPHORYL LIPID A, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN ADJUVANTED BY ASO4 ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED PRODUCED ON BACULOVIRUS HI-S RIX4446 CELLS, TRICHOPLUSIA NI. DERIVED, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN ADJUVANTED BY ASO4 ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED PRODUCED ON BACULOVIRUS HI-S RIX4446 CELLS, TRICHOPLUSIA NI. DERIVED, ALGELDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010291		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not			
EU-EC-	12/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Resolved - ) Abdominal pain (n/a	COMIRNATY	Not reported	<u>ICSR</u>
10010291			Healthcare Professional	Economic Area	available	Years	Specified			- Recovering/Resolving		·	
										- ), Fatigue (n/a - Not Recovered/Not Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (2d -			
										Recovered/Resolved - ), Nausea (n/a - Recovering/Resolving			
EU-EC-	12/10/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	- ), Vomiting (n/a - Recovering/Resolving - ) Abdominal pain (18d	COMIRNATY	NOT AVAILABLE (C - n/a -	ICSR
10010291		Spontaneous		Economic Area	available	Years	Specified	remale	NO	Recovered/Resolved - ), Amenorrhoea (18d -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - [n/a - n/a - n/a])	<u>ICSK</u>
										Recovered/Resolved - ), Appetite disorder (18d -			
										Recovered/Resolved - ), Breast pain (18d - Recovered/Resolved			
EU-EC-	12/10/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	- ) Chest pain (48h -	COMIRNATY	[TETRACYCLINE,	ICSR
10010291			Healthcare Professional	Economic	available	Years	Specified			Recovered/Resolved - ), Chest pain (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation -	TETRACYCLINE HYDROCHLORIDE] (C - Acne - n/a - [n/a - 408mg - n/a])	
										Unknown - ), Heart rate irregular			
										(n/a - Unknown - ), Hyperhidrosis (48h - Recovered/Resolved			
										- ), Pain (48h - Recovered/Resolved - ),			
										Pyrexia (48h - Recovered/Resolved - )			
EU-EC- 10010291		Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Heart rate irregular (1d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>

										-)	Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010291612	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dry skin (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF
			Troressional	Aicu						Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
										Rash pruritic (n/a - Not Recovered/Not Resolved - ),			
										Skin fissures (n/a - Not Recovered/Not Resolved - )			
EU-EC- .0010291613	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chills (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Pain (n/a - Unknown - ),			
										Pain in extremity (n/a - Unknown - ),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010291758	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Not applicable - [n/a - 1{DF} - n/a])		
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - ),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
ELL EC	12/10/2021	Snorts	Non	Euros	Net	12.17	Not	E01	Ne	Syncope (n/a - Unknown - )	COMIDNATY	Not roperted	100
EU-EC- 10010291777	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Skin bacterial infection (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- .0010292032	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
U-EC- .0010292539	12/10/2021	Spontaneous	Healthcare	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 - 1{DF} - n/a])	Not reported	ICSR

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EU-EC- 10010293806	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (3d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Pyrexia (0d - Recovered/Resolved - ),			
										Rash (0d - Recovered/Resolved - )			
EU-EC- 10010294038	12/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Troponin increased (n/a - Recovering/Resolving -)			
EU-EC- 10010294053	12/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Recovering/Resolving	n/a])		
										Hyperventilation (n/a - Recovering/Resolving			
										Paraesthesia (n/a - Recovering/Resolving - ),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tachycardia (n/a - Recovering/Resolving - )			
EU-EC- 10010294106	12/10/2021	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 -	Not reported	ICSR
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	1{DF} - n/a])		
EU-EC- 10010294120	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Injection site erythema (n/a - Recovered/Resolved - ),	1{DF} - n/a])		
										Injection site inflammation (n/a - Recovered/Resolved - ),			
										Injection site swelling (n/a - Recovered/Resolved - )			
EU-EC- 10010294185	12/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Joint range of motion decreased (n/a - Unknown - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Suspected COVID-19			

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											(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU- 100	EC- 10294258	12/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Anaphylactic reaction (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Chest discomfort (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Dizziness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),			
											Inappropriate schedule of product administration (n/a - Unknown - ),			
											Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
100	EC- 10294297	12/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU- 100	EC- 10294318	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Conversion disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
											Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
											Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
	EC- 10294611	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Inflammation (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Lethargy (n/a - Unknown - Disabling, Other Medically Important Condition),			
											Oropharyngeal pain (n/a - Unknown -			

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										Disabling, Other Medically Important Condition),			
										Sinus congestion (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10010294713	12/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Oropharyngeal 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- 10010294870	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010295097	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010296290	12/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Unknown - ), Presyncope (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010296579	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010296623	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010296636	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Papule (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010296698	12/10/2021	Spontaneous	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 - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010296702	12/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Retinal dystrophy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMENATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010296726	12/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hot flush (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010296760	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010296820	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Otitis externa (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [21d - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010296824	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Muscle twitching (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010296853	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010297084	12/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haemophagocytic lymphohistiocytosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010297103	12/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardio-respiratory arrest (n/a - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010297126	12/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

## Run Line Listing Report

							- Other Medically Important Condition)	n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 1001029713	Spontaneous	Healthcare Professional		12-17 Years	Adolescent	Male	Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR

<u>Return</u> - <u>Refresh</u> - <u>Print</u> - <u>Export</u>