## Line Listing Report Time run: 30/11/2022 10:07:17

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])	ICS Forr
:U-EC- .0010958372	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - ), Loss of consciousness (28min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010958379	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
EU-EC- 10010958390	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature decreased (n/a - Unknown - ), Capillary nail refill test abnormal (n/a - Unknown - Other Medically Important Condition), Cold sweat (133min - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Dizziness (133min - Recovered/Resolved - ), Hyperhidrosis (133min - Recovered/Resolved - ),			
										Hypotension (133min - Recovered/Resolved - Other Medically Important Condition),			
EU-EC- 10010958398	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pulse abnormal (n/a - Unknown - ) Blood pressure increased (0d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010958403	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Blood pressure increased (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010958406	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010958412	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Recovered/Resolved - ), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010958442	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010958444	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fibrin D dimer increased (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Malaise (n/a - Not Recovered/Not			

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										Resolved - Other Medically Important Condition),			
										Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010958475	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - ), Lethargy (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										- ), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Troponin increased (n/a - Recovering/Resolving - )			
EU-EC- 10010958492	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010958502	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Heavy menstrual bleeding (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Hypomenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Menstrual disorder (n/a - Unknown - Other Medically Important Condition),			
										Menstruation delayed (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Menstruation irregular (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010958519	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[IBUPROFEN, IBUPROFEN LYSINE, IBUPROFEN PH. EUR., IBUPROFEN POILUM, IBUPROFEN SODIUM DIHYDRATE] (C - Influenza, Meniscus injury - n/a - [n/a - n/a	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),		- n/a])	
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Heart rate increased (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010958523	15/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - ), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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										Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ),			
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Malaise (n/a - Recovering/Resolving - ),			
										Tachycardia (n/a - Recovering/Resolving - )			
EU-EC- 10010958535	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Heart rate increased (n/a - Not Recovered/Not Resolved - ),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010958932	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010959225	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Unknown - ),			
										Hypotension (n/a - Unknown - ),			
										Nausea (n/a - Unknown - ),			
EU-EC-	15/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Pallor (n/a - Unknown - ) Syncope (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010959250	15,12,2021	Sportaricous	Professional		available	Years	Specified	remaie		Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	The reported	ICOK
EU-EC- 10010959263	15/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a])		
										Myositis (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010959269		Spontaneous	Professional	Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
EU-EC- 10010959302	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010959303	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	C-reactive protein increased (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Lethargy (n/a - Not Recovered/Not			

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										Resolved - ), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lymphocyte count decreased (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010959312	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Chest pain (n/a - Not Recovered/Not Resolved - ),			
										Electrocardiogram ST segment depression (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Troponin I increased (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010959780	15/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Alopecia (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010959991	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition)  Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010959994	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition),	<del>                                     </del>	Not reported	ICS
										Rhinitis (n/a - Unknown - ), Troponin increased			
EU-EC- 10010960003	15/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	(n/a - Unknown - ) Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
EU-EC- 10010960009	15/12/2021	Spontaneous		Area Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICS
EU-EC- 10010960019	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically	n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICS
EU-EC- 10010960035	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No		(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
				Area						Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important	n/a])		
EU-EC- 10010960109	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
		I	1	I	1	1	1	1		Dizziness (n/a -		1	

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										Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
EU FO	45/42/2024					12.17				Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			Troop
EU-EC- 10010960198	15/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010960277	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac disorder (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Unknown - ), Illness (n/a -			
										Unknown - ),  Weight decreased (n/a - Unknown - Other Medically			
EU-EC- 10010960283	15/12/2021	Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Asthenia (32min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Economic Area						- ), Cold sweat (n/a - Recovered/Resolved - ), Fear (n/a - Unknown - ),	Not applicable - [1d - n/a - Intramuscular])		
										Loss of consciousness (32min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010960284	15/12/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010960293	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Syncope (30min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10010960297	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a -	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a -			
EU-EC-	15/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Recovered/Resolved - Caused/Prolonged Hospitalisation) Headache (25min -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010960309	, ., .,	,	Professional		available	Years	Specified			Recovered/Resolved - ), Syncope (25min - Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	, .	
EU-EC-	15/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	- Other Medically Important Condition) Blood pressure	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010960320			Professional		available	Years	Specified			increased (n/a - Unknown - ),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	•	

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										Dizziness (65min - Recovered/Resolved - ),			
										Syncope (65min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010960323	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010960326	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ), Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										- Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation),  Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010960337	15/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Fatal - Results in Death),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Headache (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal	Intramuscular])		
EU-EC- 10010960339	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Results in Death) Dizziness (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
				7.4.00						Sensation of foreign body (n/a - Recovered/Resolved - Other Medically Important Condition)	and an escalar jy		
EU-EC- 10010960355	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010960368	15/12/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Syncope (3min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10010960372	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Face oedema (n/a - Not Recovered/Not Resolved - ),	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Nephrotic syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically			
EU-EC- 10010960382	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Hypoglycaemia (n/a - Unknown - ), Hypotension (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010960388	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010960404	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (55min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010960407	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010960408	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition) Epilepsy (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Seizure (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			

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EU-EC- 10010960411	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (45min - Recovered/Resolved - ), Loss of consciousness (45min - Recovered/Resolved - Other Medically Important Condition), Nausea (45min - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Syncope (45min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010960470	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	·	<u>IC</u>
:U-EC- .0010960472	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - ), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>IC</u>
:U-EC- 0010960482	15/12/2021	Spontaneous	Hea <b>l</b> thcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Not Recovered/Not Resolved - ), Rash maculo-papular (n/a - Not Recovered/Not Resolved - ), Upper gastrointestinal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
U-EC- 0010960492	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Erythema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  Rash (n/a -	Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
U-EC- 0010960495	15/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving - Caused/Prolonged Hospitalisation) Carditis (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	10
				Economic Area			,				Not applicable - [n/a - n/a - n/a])		
EU-EC- 1.0010960499	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cerebral venous sinus thrombosis (1d - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),  Cerebral venous sinus thrombosis (1d - Unknown - Life Threatening, Disabling, Other Medically Important Condition),  Circulatory collapse	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	10
										(1d - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition), Eye movement			
										disorder (1d - Unknown - Life Threatening, Disabling, Other Medically Important Condition),			
										Haemorrhage (n/a - Unknown - Life Threatening, Disabling), Pallor (0d -			
										Pallor (ud - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition), Respiration abnormal			

12/2021 Spo	ontaneous He Pr	lealthcare rofessional	European Economic Area	Not available Not available	12-17	Not Specified	Female	No No	Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICSR
12/2021 Spo	ontaneous H Pr	lealthcare rofessional	European Economic Area  Non European Economic	available  Not	Years	Specified			Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),  Somnolence (1d - Unknown - Life Threatening, Disabling, Other Medically Important Condition),  Tongue biting (n/a - Unknown - Life Threatening, Disabling),  Tremor (n/a - Unknown - Life Threatening, Disabling),  Tremor (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition),  Unresponsive to stimuli (n/a - Unknown - Life Threatening, Disabling) Disabling, Other Medically Important Condition),  Unresponsive to stimuli (n/a - Unknown - Life Threatening, Disabling) Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)  Bradycardia (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
12/2021 Spo	ontaneous H Pr	lealthcare rofessional	European Economic Area  Non European Economic	available  Not	Years	Specified			Unknown - Life Threatening, Disabling, Other Medically Important Condition), Tongue biting (n/a - Unknown - Life Threatening, Disabling), Tremor (n/a - Unknown - Life Threatening, Disabling), Unknown - Life Threatening, Disabling, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Disabling) Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
12/2021 Spo	ontaneous H Pr	lealthcare rofessional	European Economic Area  Non European Economic	available  Not	Years	Specified			Unknown - Life Threatening, Disabling), Tremor (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Disabling) Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
12/2021 Spo	ontaneous H Pr	lealthcare rofessional	European Economic Area  Non European Economic	available  Not	Years	Specified			Unknown - Life Threatening, Disabling, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Disabling) Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Recovered/Not Resolved - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
12/2021 Spo	ontaneous H Pr	lealthcare rofessional	European Economic Area  Non European Economic	available  Not	Years	Specified			stimuli (n/a - Unknown - Life Threatening, Disabling) Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Bradycardia (n/a - Whedically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
12/2021 Spo	ontaneous H Pr	lealthcare rofessional	European Economic Area  Non European Economic	available  Not	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
	Pr	rofessional	European Economic				Female	No	Recovered/Not Resolved - Other Medically Important Condition) Bradycardia (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
	Pr	rofessional	European Economic				Female	No	Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
2/2021 Spoo									Depressed level of			
2/2021 Spor									consciousness (n/a - Unknown - Other Medically Important Condition),			
2/2021 Spo									Dizziness (n/a - Unknown - )			
2/2021 300		rofessional		Not available	12-17 Years	Not Specified	Female	No	Tonic convulsion (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
.2/2021 Spo	ontaneous He Pr	rofessional		Not available		Not Specified	Male	No	Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
									Condition), Tubulointerstitial nephritis (n/a - Unknown - Other Medically Important			
.2/2021 Spor		rofessional		Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving	(S - COVID-19 immunisation -	Not reported	ICSR
									Chest discomfort (n/a - Recovering/Resolving - ),			
									Chest pain (n/a - Recovering/Resolving - ), Confusional state			
									(n/a - Recovering/Resolving - ), Dyspnoea (n/a -			
									Recovering/Resolving - ), Gait disturbance (n/a			
									Recovering/Resolving - ), Headache (n/a - Recovering/Resolving			
									- ), Hypotension (n/a - Recovering/Resolving - ),			
									Nausea (n/a - Recovering/Resolving - ),			
2/2	2021 Spc	P	Professional	Professional European Economic	Professional European Economic Area available	Professional European Economic Area Professional European Economic Area	Professional European Economic Area Specified	Professional Economic Area available Years Specified	Professional European Economic Area Specified	Spontaneous   Healthcare Professional   European Economic Area   Not Area   Specified   Specified	2021 Spontaneous Healthcare Professional Area  Non Professional Economic Area  Not Professional Economic Area  Comitonal State (n/a - Recovering/Resolving - ),  Dyspnoea (n/a - Recovering/Resolving - ),  Gait disturbance (n/a - Recovering/Resolving - ),  Headache (n/a - Recovering/Resolving - ),  Hypotension (n/a - Recovering/Resolving - ),  Not Professional Economic Area  Comitonal State (n/a - Recovering/Resolving - ),  Hypotension (n/a - Recovering/Resolving - ),  Not Professional Economic Area  Not Pr	2021 Spontaneous Healthcare Professional European Europea

	15/12/2021	Spontaneous		European	Not	12-17 Years	Not	Female	No	Recovering/Resolving - Other Medically Important Condition) Abdominal pain (n/a	COMIRNATY [TOZINAMERAN]	Not reported	<u>IC</u>
.0010960615			Healthcare Professional	Economic Area	available	Years	Specified			- Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [A/HONG KONG/4801/2014		
										Resolved - ),  Headache (1d - Recovered/Resolved	(H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE		
										- ), Injection site pain (2d -	STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED		
										Recovered/Resolved - ),	STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN		
										Malaise (n/a - Recovering/Resolving - ),	(A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN		
										Nausea (n/a - Not Recovered/Not Resolved - )	(B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA		
											VACCINE] (S - Influenza immunisation - Not applicable - [n/a - 1{DF} - n/a])		
0010960616		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(10d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
J-EC- 0010960624	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	
										Menstruation irregular (n/a - Recovering/Resolving -)			
J-EC- 0010960926	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ),	COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	
										Headache (0d - Recovering/Resolving - ),			
										Myocarditis (0d - Recovering/Resolving - ), Pyrexia (0d -			
U-EC-	15/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Recovering/Resolving - )  Arthralgia (n/a -	COMIRNATY [TOZINAMERAN]	METHOTREXATE	_
0010960959	, ,	, ·	Professional	Economic Area	available	Years	Specified			Recovered/Resolved - ), Condition aggravated	(S - Immunisation - Unknown - [n/a3mL - Intramuscular])	[METHOTREXATE] (C - n/a - Drug withdrawn - [n/a - 10mg - Unknown])	J
										(n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovered/Resolved - ),			
										Hepatosplenomegaly (n/a - Unknown - ),			
										Joint swelling (n/a - Recovered/Resolved - ),			
										Microcytic anaemia (n/a - Unknown - ),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
U-EC-	15/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Thrombocytopenia (n/a - Unknown - ) Loss of	COMIRNATY [TOZINAMERAN]	Not reported	_
0010961250			Professional	Economic Area	available	Years				consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [1d - n/a - n/a])	,	
										Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation)			
U-EC- 0010961260	15/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Child	Male	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	
										Back pain (n/a -			

30.11.2022	10.24								Vall Li	ne Listing repor			
										Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically			
										Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Lymphadenitis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nasal congestion (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Orchitis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pharyngitis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 1001096140		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	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	<u>ICSR</u>
EU 50	45/42/2024					10.17		- 1		(n/a - Unknown - Other Medically Important Condition)			roop
EU-EC- 1001096189		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Application site pain (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 1001096195		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 1001096197	15/12/2021	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 - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Menstruation irregular (n/a - Not Recovered/Not Resolved - )			
EU-EC- 1001096199		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Coronary artery dilatation (n/a - Unknown - Caused/Prolonged			

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										Hospitalisation),  Electrocardiogram repolarisation abnormality (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Mitral valve incompetence (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010962134	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Male	No	Asthenia (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA	Not reported	ICSR
			roressioner	71100						Chills (n/a -	VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -		
										Decreased appetite (n/a - Recovering/Resolving - ),	n/a])		
										Delirium (n/a - Recovering/Resolving - ),			
										Dizziness (n/a - Recovering/Resolving - ),			
										Headache (n/a - Recovering/Resolving - ),			
										Hyperhidrosis (n/a - Recovering/Resolving - ),			
										Nausea (2d - Recovering/Resolving - ),			
										Pallor (n/a - Recovering/Resolving - ),			
										Somnolence (n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving			
EU-EC- 10010962365	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010962621	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
EU-EC- 10010962653	15/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),		NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Myalgia (2d - Recovered/Resolved - ),	, -1/		
										Nausea (n/a - Recovering/Resolving - )			
EU-EC- 10010963145	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010963539	15/12/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a]	ICSR
EU-EC- 10010963572	15/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Encephalitis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
										Pleocytosis (n/a - Unknown - ),			

).11.2022 <sup>-</sup>	10.24							-	Kun Li	ne Listing Repo	ı		
										Protein total increased (n/a - Unknown - ),			
										Seizure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010963576	15/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10010963853	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010963858	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 immunisation (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Dyskinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- L0010963882	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
										Urinary tract infection bacterial (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010964014	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Headache (n/a - Recovering/Resolving - ),	.,, 2])		
										Injection site inflammation (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Injection site swelling (n/a - Not Recovered/Not Resolved - ),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010964639	15/12/2021	Spontaneous	Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICS</u>
										Cold sweat (n/a - Not Recovered/Not Resolved - ),			
										Fatigue (n/a - Unknown - ),			
										Feeling of body temperature change (n/a - Unknown - ),			
										General physical health deterioration (n/a - Not Recovered/Not Resolved - ),			
										Hot flush (n/a - Unknown - ),			
										Hyperhidrosis (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Unknown - ),			
			  ytics/saw.	41120-						Pyrexia (n/a - Not			 12/

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										Recovered/Not Resolved - ), Vaccination site pain			
										(n/a - Not Recovered/Not Resolved - ), Vaccination site pain			
EU-EC- 10010965019	15/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	(n/a - Unknown - ) Epistaxis (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	IC
			Troicissional	74.63						Glomerulonephritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Hypertension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Renal failure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010965020	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	10
										Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Menstrual disorder (n/a - Recovered/Resolved -),			
										Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Skin exfoliation (n/a - Recovered/Resolved			
EU-EC- 10010965108	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- )   Multisystem   inflammatory   syndrome in children   (n/a - Recovering/Resolving   Life Threatening,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	10
EU-EC-	15/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Malo	No	Caused/Prolonged Hospitalisation) Myopericarditis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	10
10010965224	13/12/2021	Sportaneous	Professional	Economic Area	available	Years	Adolescent	Мане		Recovered/Resolved - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010965274	15/12/2021	Spontaneous		European Economic Area	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 - [1d - 1{DF} - Intramuscular])	Not reported	<u>I</u>
										Dyspnoea exertional (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sleep disorder (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10010965685	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Pyrexia (n/a - Recovered/Resolved - ),  Vomiting (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	<u>I</u>
EU-EC-	15/12/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Resolved - ) Abdominal distension	(S - n/a - n/a - [n/a - n/a - Intramuscular])  COMIRNATY [TOZINAMERAN]	Not reported	<u> </u>
10010965735	, <del>-</del>		Healthcare Professional	Economic	available	Years	Specified			(n/a - Not Recovered/Not Resolved - ),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Eye irritation (n/a - Not Recovered/Not Resolved - ), Eye pain (n/a - Not			

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											Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ),			
											Injection site inflammation (3d - Recovered/Resolved - ),			
											Injection site pain (3d - Recovered/Resolved - ),			
											Injection site warmth (3d - Recovered/Resolved - ),			
											Malaise (n/a - Not Recovered/Not Resolved - ),			
											Myalgia (3d - Recovered/Resolved - ), Paraesthesia (3d -			
											Recovered/Resolved - ),  Pyrexia (n/a -			
	EU-EC-	15/12/2021	Spontaneous		Non	Not	12-17	Not	Female	No	Recovered/Resolved - ) Syncope (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	10010965908 EU-EC-	15/12/2021	Spontaneous	Professional Non	European Economic Area Non	available Not	Years 12-17	Specified Not	Male	No	- Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	10010965939	19,12,2021	эролипевия		European	available	Years	Specified	, idie		Recovered/Not Resolved - Other	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	The reported	10011
											Chest pain (n/a - Unknown - Other Medically Important Condition),			
											Cough (n/a - Unknown - Other Medically Important Condition),			
											Dyspnoea (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10010966034	15/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
											Erythema (n/a - Recovering/Resolving - ),			
											Lip swelling (n/a - Recovering/Resolving - ),			
											Oropharyngeal discomfort (n/a - Recovering/Resolving - ),			
											Pemphigus (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Peripheral swelling (n/a - Recovering/Resolving -),			
											Post inflammatory pigmentation change (n/a - Recovering/Resolving			
											- ), Pruritus (n/a - Recovering/Resolving			
											- ), Sensitive skin (n/a - Recovering/Resolving - )			
	EU-EC- 10010966126	15/12/2021	Spontaneous			Not available		Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
														1 1

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											Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Suspected COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Vaccination site joint movement impairment (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10010966168	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (4min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Seizure (0d - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10010966180	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
	EU-EC- 10010966202	15/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Fatigue (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Illness (n/a - Unknown - Other Medically Important Condition),			
											Malaise (n/a - Unknown - Other Medically Important Condition),			
											Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
											Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
	EU-EC- 10010966219	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (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),			
											Myocarditis (n/a - Unknown - Other Medically Important Condition),			
											Presyncope (0d - Recovered/Resolved - Other Medically Important Condition),			
											Syncope (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10010966233	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	Not reported	ICSR
											Decreased appetite (n/a - Unknown - Other Medically Important Condition),			
											Headache (7d - Recovered/Resolved - Other Medically Important Condition),			
											Hypersomnia (7d - Recovered/Resolved			

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										- Other Medically Important Condition),			
										Illness (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (7d - Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0010966451	15/12/2021	Spontaneous	Hea <b>l</b> thcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										Vaccination site bruising (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site induration (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
J-EC- 0010966466	15/12/2021	Spontaneous	Hea <b>l</b> thcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	Not reported	
J-EC- 0010966553	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Vaccination failure (10d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	
J-EC- 0010966947	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved - ), Syncope (n/a -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	
U-EC- 0010966951	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved - ) Gastrointestinal disorder (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [31d - 1{DF}	Not reported	_
U-EC- 0010966974	15/12/2021	Spontaneous	Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Rash (n/a - Recovering/Resolving - )	- Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	_
U-EC- 0010966990	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	
U-EC- 0010966998	15/12/2021	Spontaneous	Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - ) Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	_
U-EC- 0010967072	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	Yes	Menstrual disorder (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	
U-EC- 0010967235	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown - )	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]),	Not reported	_
											M-M-RVAXPRO [MEASLES VIRUS ENDERS' EDMONSTON STRAIN (LIVE, ATTENUATED), MUMPS VIRUS JERYL LYNN (LEVEL B) STRAIN (LIVE, ATTENUATED), RUBELLA VIRUS WISTAR RA 27/3 STRAIN (LIVE, ATTENUATED), RUBELLA VIRUS WISTAR RA		
											27/3 STRAIN (LIVE, ATTENUATED) PRODUCED IN WI-38 HUMAN DIPLOID LUNG FIBROBLASTS, MUMPS VIRUS JERYL LYNN (LEVEL B) STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS, MEASLES VIRUS EDMONSTON-ENDERS		
											STRAIN (LIVE, ATTENUATED) PRODUCED IN CHICK EMBRYO CELLS] (S - Immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]),		
											NIMENRIX [N. MENINGITIDIS		

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											GROUP C (STRAIN C11) POLYSACCHARIDE (DE-O- ACETYLATED) CONJUGATED TO TETANUS TOXOID, NEISSERIA MENINGITIDIS GROUP A POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP W-135 POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP Y-0155 GROUP Y-0155 GROUP Y-0155 GROUP Y-0155 GROUP Y-0155 GROUP Y-0156 GROUP Y-		
EU-EC- 10010967270	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovered/Resolved - ), Injection site pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010967335	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- ) Abdominal pain (n/a - Recovering/Resolving - ), Influenza like illness (n/a - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010967337	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ),  Menstrual disorder (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	[MEDROGESTONE] (C - Pelvic pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010967344	15/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - ) Lymphadenitis (48h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010967354	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (10d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010967979	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - ),  Dizziness (n/a - Not Recovered/Not Resolved - ),  Dyspnoea (n/a - Not Recovered/Not Resolved - ),  Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Myalgia (n/a - Not Recovered/Not Resolved - ),  Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pyrexia (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 - ),  Tachycardia (n/a - Not Recovered/Not Resolved - ),  Tachycardia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010967991		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - ) Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010968010		Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>

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				Economic Area						Resolved - ),	Not applicable - [n/a - n/a - n/a])		
										Dyspnoea (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Lethargy (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site reaction (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010968013	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010968018	15/12/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	n/a])		
EU-EC- 10010968038	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss 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	ICSR
										Pallor (n/a - Unknown - )			
EU-EC- 10010968097	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pleurisy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010968102	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Electrocardiogram ST segment elevation (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010968113	15/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
				/ Ted						abnormal (n/a - Unknown - ),	1,73])		

										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - ),			
										Pain in jaw (n/a - Unknown - ),			
										Troponin increased (n/a - Unknown - )			
EU-EC- 10010968115	15/12/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Headache (0d - Recovered/Resolved With Sequelae - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSI
			Professional	Area						Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	Not applicable - [10 - n/a - n/a])		
										Memory impairment (n/a - Unknown - ),			
										Muscle rigidity (n/a - Unknown - ),			
										Nausea (n/a - Recovering/Resolving - ),			
:U-EC-	15/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Tremor (n/a - Unknown - ) Pericarditis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
0010968117	13/12/2021	Sportaneous		European Economic Area	available	Years	Specified	Male	INO	Unknown - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	10.3
U-EC- 0010968239	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination failure (n/a - Unknown - )		Not reported	ICS
:U-EC- 0010968289	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
	15/12/2021	Spontaneous		Non	Not		Not	Male	No	Condition) Chest discomfort		Not reported	ICS
0010968290			Professional	European Economic Area	available	Years	Specified			(n/a - Recovered/Resolved - ), Chest pain (n/a - Recovered/Resolved - ),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-	15/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition) Syncope (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010968299			Professional	European Economic Area	available	Years	Specified	remale		Recovered/Resolved - Other Medically	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	
EU-EC- 10010968304		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICS
EU-EC- 10010968305	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICS</u>
										Unresponsive to stimuli (n/a - Fatal - Results in Death)			
EU-EC- L0010968314	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(20min - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Pallor (20min - Recovered/Resolved - ),			
										Syncope (20min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010968318	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - ), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICS</u>
										Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0010968324	15/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
					1	I	1	I	1	Drug ineffective (n/a			

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EU-EC- 10010968325	15/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Unknown - ) Blood pressure increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
				Economic Area							Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10010968326	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010968327	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Pericarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010968329	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heart rate increased (n/a - Unknown - ), Hypersensitivity (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Hyperventilation (n/a - Recovering/Resolving - Other Medically Important			
										Condition),  Rash (n/a - Recovering/Resolving - )			
EU-EC- 10010968330	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICS</u>
										Nasopharyngitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010968375	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (3min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010968396	15/12/2021	Spontaneous	Healthcare Professional	Non	Not available	12-17 Years	Not Specified	Female	No	Pruritus (30min - Recovered/Resolved - ), Syncope (30min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010968417	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - ), Electrocardiogram ST segment elevation	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICS</u>
										(n/a - Unknown - Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - ), Troponin increased			
										(n/a - Unknown - ),  Vaccination site pain (n/a - Unknown - )			
EU-EC- 10010968418	15/12/2021	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 - n/a])	Not reported	ICS
EU-EC- 10010968838	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Headache (2d - Not Recovered/Not Resolved - ), Pyrexia (2d - Not	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN]	Not reported	ICS
										Recovered/Not Resolved - ),  Vaccination site erythema (2d - Not	(S - C Immunisation - Not applicable - [n/a3mL - Intramuscular])		
										Recovered/Not Resolved - ), Vaccination site pain (2d - Not			
EU-EC-	15/12/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010969529	,,	, , , , , , , , , , , , , , , , , , , ,	Healthcare Professional	European	available	Years	Specified			(n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		2001

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										Urticaria (n/a - Recovered/Resolved - )			
EU-EC- 10010969589	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - ), Nausea (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Seizure (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - )			
EU-EC- 10010969600	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010969635	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Arthritis (n/a - Recovering/Resolving - ),			
										Dermatitis allergic (n/a - Recovering/Resolving - ),			
										Joint stiffness (n/a - Not Recovered/Not Resolved - ),			
										Psoriasis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Psoriatic arthropathy (n/a - Recovering/Resolving - Disabling)			
EU-EC- 10010969828	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Recovered/Resolved -), Presyncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSE
										Recovered/Resolved -), Syncope (n/a - Recovered/Resolved			
										- Other Medically Important Condition)			
EU-EC- 10010970002	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (12d - Recovered/Resolved -), Injection site pain	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										(4d - Recovered/Resolved			
EU-EC- 10010970038	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tubulointerstitial nephritis (124d - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010970041	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation)  Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged	outer inde specifica/j/		
										Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Visual impairment (n/a - Not Recovered/Not			
EU-EC- 10010970043	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - )  Traumatic haemothorax (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010970106		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		ICSR
EU-EC- 10010970230	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Malaise (5d - Recovering/Resolving			
:U-EC- 0010970240	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
U-EC- 0010970273	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	<u>IC:</u>
										Vaccination site irritation (1d - Recovered/Resolved -)			
U-EC- 0010970310	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved - ), Dizziness (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Recovered/Resolved - ), Fatique (3d -			
										Recovered/Resolved - ), Feeling hot (3d -			
										Recovered/Resolved - ), Headache (3d -			
										Recovered/Resolved - ), Influenza (2d - Recovered/Resolved			
										- ), Injection site pain (3d -			
										Recovered/Resolved - ), Limb discomfort (1d			
										Recovered/Resolved - ), Malaise (3d -			
										Recovered/Resolved - ), Nausea (1d -			
										Recovered/Resolved - ), Pyrexia (1d -			
EU-EC- .0010970537	15/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	IC
				Economic Area						Hospitalisation),  Immunisation (n/a - Unknown -	Not applicable - [1d - n/a - Intramuscular])		
										Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown -			
EU-EC-	15/12/2021	Spontaneous		European	Not	12-17	Not	Male	No	Caused/Prolonged Hospitalisation) Nasal congestion	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010970732 EU-EC-	15/12/2021	Spontaneous	Professional Healthcare	Non	available Not	Years 12-17	Specified Not	Not	No	(n/a - Not Recovered/Not Resolved - ) Arthritis (n/a -	(S - n/a - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN]	Not reported	ICS
.0010971007			Professional	European Economic Area	available	Years	Specified	Specified		Unknown - ),  Dry eye (n/a - Not Recovered/Not Resolved - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Condition), Inappropriate schedule of product administration (n/a - Unknown - ),			
										Joint stiffness (n/a - Unknown - ),			
										Psoriasis (n/a - Unknown - ), Tendonitis (n/a -			
:U-EC- :0010971221	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown - ) Injection site erythema (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>IC</u>
U-EC- 0010971289	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
U-EC- 0010971304	15/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (6d - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	IC

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										Myocarditis (6d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010971326	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010971651	15/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation)  Altered state of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Atrioventricular block (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fall (n/a - Unknown - Other Medically Important Condition),			
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Seizure (2min - Recovered/Resolved - Other Medically Important Condition),			
										Skin laceration (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010971787	15/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Unknown - ), COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Chest discomfort (n/a - Unknown - ),			
										Cough (n/a - Unknown - ),			
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - ),			
										Mitral valve incompetence (n/a - Unknown - Other Medically Important Condition),			
										Mitral valve prolapse (n/a - Unknown - ),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - ),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rhinitis allergic (n/a - Unknown - ),			
										Sinus tachycardia (n/a - Unknown - ),			
										Syncope (10s - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010972200	15/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010972606	15/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR

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Section   Sect		15/12/2021	Spontaneous	Healthcare	Economic		Male	No	Unknown - ), Herpes zoster (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Unknown	19 immunisation - Not	VACCINE] (C - n/a - n/a - [n/a -	ICSR
Company   Comp		14/12/2021	Spontaneous		Economic		Female	No	Ascites (45d - Recovered/Resolved - Other Medically Important	(S - COVID-19 prophylaxis - Dose not changed - [n/a -	Not reported	ICSR
Part									Asthenia (45d - Recovered/Resolved - Other Medically Important	(S - COVID-19 prophylaxis - Drug withdrawn - [n/a5mL		
File												
BL-EC   M-1/2/201   Spotterous   Rath Professional Resource   Rath Resource									- Other Medically Important			
Report   R									Recovered/Resolved - Other Medically Important			
RELIFICATION   Processor   P									Recovered/Resolved - Other Medically Important			
Recovered Number   Recovered N									Recovered/Resolved - Other Medically Important			
									Recovered/Resolved - Other Medically			
EU-EC-   14/12/2021   Sportlameous   Healthcare   European   Not   12-17   Not   Sportlameous   Healthcare   Professional   Economic   Area   Not   Professional   Area   Not   Professional   Economic   Area   Not   Professional   Area   Not   Professional   Economic   Area   Not   Professional   Economic   Not   Professional   Economic   Area   Not   Professional   Economic   Not   Professional   Economic   Not   Professional   Economic   Not   Professional   Economic   Not   Pro		14/12/2021	Spontaneous	Healthcare	Economic		Male	No	(n/a - Not Recovered/Not	(S - COVID-19 immunisation - n/a - [n/a3mL -		ICSR
EU-EC- 10/10/4322   Spontaneous   Non- Nealthcare   European   Not   Note   Specified   Non- Note   Sp									Noninfective gingivitis (n/a - Not Recovered/Not	Intramuscular])		
EU-EC-									eruption (n/a - Not Recovered/Not			
Recovered/Resolved   Continue   Recovered/Resolved   Continue   Recovered/Resolved   Continue   Recovered/Resolved   Continue   Recovered/Resolved   Continue   Con		14/12/2021	Spontaneous	Healthcare	Economic		Male	No	Pain in extremity (0d - Recovered/Resolved - ),	(S - COVID-19 immunisation - n/a - [n/a - 30ug -	Not reported	ICSR
EU-EC   14/12/2021   Spontaneous   Non   Healthcare   European   Not   12-17   Not   Specified   Not   12-17   Not   N									Recovered/Resolved - )			
ELF-EC- 10010945332		14/12/2021	Spontaneous		Economic		Female	No	Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation -	Not reported	ICSR
EU-EC- 10010945332   14/12/2021   Spontaneous Nom tealthcare Professional   Leveriace Profession									Unknown - Other Medically Important			
Professional Frofessional Professional Frofessional Professional Professional Area  Professional Professional Frofessional Area  Professional Professional Frofessional Area  Professional Professional Frofessional Frofessional Professional		14/12/2021	Spontaneous	Healthcare	Economic		Male	No	Epilepsy (n/a - Recovered/Resolved - Other Medically	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	[LEVETIRACETAM] (C - Epilepsy -	ICSR
EU-EC-   10010945413   Spontaneous   Frofessional   EU-EC-   10010945414   Purple   Frofessional   Frofessional   Purple   Frofessional   Frofessional   Purple   Frofessional   Frofessional   Frofessional   Purple   Frofessional		14/12/2021	Spontaneous		Economic		Female	No	Recovering/Resolving - Caused/Prolonged	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010945413									Recovering/Resolving - Caused/Prolonged			
Healthcare Professional   Healthcare Profe									(n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10010945414   Spontaneous   Non Healthcare Professional   Non Syncope (n/a - Non Recovered/Not Recovered/Not Recovered/Not Resolved - Other Medically Important   Non applicable - [n/a - n/a - n/a]   Not reported   ICSR   ICSR		14/12/2021	Spontaneous	Healthcare	Economic		Female	No	Unknown - ), Pyrexia (n/a -	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 101010945613   Spontaneous   Healthcare   Professional   European   Economic   Area   Specified   Specified		14/12/2021	Spontaneous	Healthcare	Economic		Male	No	Diarrhoea (n/a -	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
		14/12/2021	Spontaneous		European Economic			No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR

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EU-EC- 10010946051	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - ), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010946067	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Troponin increased	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Recovered/Resolved - )			
EU-EC- 10010946076	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Musculoskeletal stiffness (n/a - Recovered/Resolved - ), Oropharyngeal pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										(n/a - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved			
EU-EC- 10010946108	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - ), Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010946635	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (495min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (495min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Feeling abnormal (490min - Recovered/Resolved - ),			
										Hypoaesthesia (485min - Recovered/Resolved - ),			
										Menstrual discomfort (495min - Recovered/Resolved - ),			
										Nausea (490min - Recovered/Resolved - ),			
										Physical deconditioning (495min - Recovered/Resolved -),			
										Tremor (495min - Recovered/Resolved - )			
EU-EC- 10010946803	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (675min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Blood pressure decreased (675min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Erythema (675min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Pallor (n/a -			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010946896	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

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EU-EC- 10010946962	14/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chest pain (n/a - Unknown - ), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Unknown - ),  Musculoskeletal chest pain (n/a - Unknown - ),			
										Myalgia (n/a - Unknown - ),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10010947019	14/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Child	Female	No	Condition) Hypersensitivity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICS
EU-EC- 10010947021	14/12/2021	Spontaneous		Area European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Recovering/Resolving - Disabling),	Intramuscular])  COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICS
				Alea						Exercise tolerance decreased (n/a - Recovering/Resolving	Intranscular J		
										- Disabling), Fatigue (n/a - Recovering/Resolving - Disabling),			
										Leukopenia (n/a - Recovering/Resolving - Disabling),			
										Neutropenia (n/a - Recovering/Resolving - Disabling),			
										Pyrexia (n/a - Recovering/Resolving - Disabling)			
EU-EC- 10010947035	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010947509	14/12/2021	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	ICS
EU-EC- 10010947538	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Hypotonic- hyporesponsive episode (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010947589	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICS
										Eyelid disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Eyelid irritation (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vision blurred (n/a - Unknown - Caused/Prolonged Hospitalisation)			
		Spontaneous	Non	European	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
EU-EC- 10010947869	14/12/2021	·	Healthcare Professional	Economic Area	avaliable	l				Resolved - ), Fatigue (n/a - Not	Not applicable - [n/a - 1{DF} - n/a])		

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										Headache (n/a - Recovering/Resolving - ),			
										Injection site inflammation (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not Recovered/Not Resolved - ),			
										Injection site warmth (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Recovering/Resolving - ),			
										Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - ),			
EU-EC-	14/12/2021	Constant	I I a a libba a a sa		Note	12.17	Note	F	N-	Pyrexia (n/a - Recovering/Resolving - )	COMIDNATY CONCENTRATE	Not were the d	TCCD
10010947902	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - 1]Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	intramescular j		
										Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010948146	14/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )		ANTICONCEPTIEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
EU-EC- 10010948340	14/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not	COMIRNATY [TOZINAMERAN]	[ALLERGEN EXTRACT, ALLERGENS, POLLEN & PLANT EXTRACT, ALNUS GLUTINOSA L., AMBROSIA ARTEMISIIFOLIA, ANTHOXANTHUM ODORATUM L., ARTEMISIA VULGARIS L., AVENA FATUA WHOLE., BROMUS INERMIS WHOLE, BROMUS INERMIS WHOLE, DACTYLIS GLOMERATA L., PHLEUM PRATENSE L., ANTHOXANTHUM ODORATUM L., LOLIUM PERENNE L., POA PRATENSIS L., HOLCUS LANATUS, FESTUCA PRATENSIS HUDSON, AGROSTIS CAPILLARIS L., CYNODON DACTYLON (L.) PERS., ARRHENATHERUM ELATIUS, AVENA SATIVA L., TRITICUM AESTIVUM, DACTYLIS GLOMERATA L., PHLEUM PRATENSE L., ANTHOXANTHUM ODORATUM L., LOLIUM PERENNE L., HORDEUM VULGARE L., AVENA SATIVA L., TRITICUM AESTIVUM, ZEA MAYS L., HORDEUM VULGARE L., BETULA, POLLEN EXTRACT, ALNUS GLUTINOSA POLLEN EXTRACT, BETULA, CORYLUS AVELLANA L., ALNUS GLUTINOSA L., BERTULA, CORYLUS AVELLANA L., ALNUS GLUTINOSA L., BERTULA, CORYLUS AVELLANA L., ALNUS GLUTINOSA L., CARPINUS BETULUS L., CAT EPITHELIA, CORYLUS AVELLANA L., CORYLUS AVELLANA L., BETULA PENDULA ROTH., ALNUS GLUTINOSA L., CYNODON DACTYLON (L.) PERS., DACTYLIS GLOMERATA L., PHLEUM DORATUM L., LOLIUM PERENNE L., POA PRATENSIS L., DACTYLIS GLOMERATA L., PHLEUM	ICSR

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												PTERONYSSINUS, DERMATOPHAGOIDES PTERONYSSINUS, DERMATOPHAGOIDES FARINAE, DOG EPITHELIA, FRAXINUS EXCELSIOR L., HAZEL POLLEN ALLERGOID FORMALDEHYDE MODIFIED, ALDER POLLEN ALLERGOID FORMALDEHYDE MODIFIED, BIRCH POLLEN ALLERGOID GLUTARALDEHYDE MODIFIED, BIRCH POLLEN ALLERGOID GLUTARALDEHYDE MODIFIED, JUNIPERUS ASHEI BUCHHOLZ, LOLIUM PERENNE L., OLEA EUROPAEA L., PARIETARIA JUDAICA L., PARIETARIA JUDAICA L., PARIETARIA OFFICINALIS L., PHLEUM PRATENSE L., POA PRATENSIS L., SECALE CEREALE L.] (C - n/a - Dose not changed - [n/a - 1[drp] - Oral])	,
:U-EC- .0010948418	14/12/2021	Spontaneous		European Economic Area	Not available		Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), 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	ICS
:U-EC- .0010948456	14/12/2021	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	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010948788	14/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other			
	14/12/2021	Spontaneous		Non	Not		Not	Female	No	Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010948870 EU-EC-	14/12/2021	Spontaneous		European Economic Area Non	available Not	Years	Specified Not	Not	No	- Other Medically Important Condition) Aphthous ulcer (n/a -		Not reported	ICS
	14/12/2021	Spontaneous	Non	European Economic Area	available	Years 12-17	Specified	Specified	No	Not Recovered/Not Resolved - ), Lethargy (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ), Pain in jaw (n/a - Not Recovered/Not Resolved - ), Pain in jaw (n/a - Not Recovered/Not Resolved - ), Petechiae (n/a - Not Recovered/Not Resolved - ), Thrombocytopenia (n/a - Not Recovered/Not Resolved - ), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Migraine (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
10010949091	14/12/2021	Spontaneous	Healthcare	Economic Area	available		Specified	Male	INO	Recovering/Resolving	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	10.
EU-EC- 1.0010949171	14/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - Other	- I/Jaj COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICc

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										- Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010949195	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010949750	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Neck pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010949753	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										- ), Heavy menstrual bleeding (7d - Recovered/Resolved			
										- ), Malaise (1d - Recovered/Resolved - ), Nausea (1d -			
										Recovered/Resolved - ), Polymenorrhoea (76d -			
FU 50						10.17				Recovered/Resolved		Inconstruction in	1000
EU-EC- 10010949756	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL] (C - Heavy menstrual bleeding - n/a - [n/a - n/a - n/a])	ICSR
										Menstruation irregular (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010949761	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										- Unknown - Other Medically Important Condition), Peripheral coldness (1d -			
EU-EC-	14/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Recovered/Resolved - ) Head injury (n/a -	COMIRNATY CONCENTRATE	Not reported	ICSR
10010950186	14/12/2021	Spontaneous	Professional		available	Years	Specified	male	INO	Unknown - Caused/Prolonged Hospitalisation), Loss of	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL -	Not reported	ICSK
										consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash rubelliform (n/a	Intramuscular])		
										- Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a -			
EU = 2	1400000					40.00				Unknown - Caused/Prolonged Hospitalisation)	LOOUTDUIT 17-0-1		-
EU-EC- 10010950523	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Headache (7d - Not Recovered/Not Resolved - ), Pyrexia (7d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010950625	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - ) Pericarditis (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[COLCHICINE] (C - n/a - n/a - [n/a75mg - Oral])	ICSR
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EU-EC- 10010950850	14/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Asthenia (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),			
										Illness (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010950911	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Swelling (n/a - Not Recovered/Not Resolved - )	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[SERTRALINE] (C - n/a - Dose not changed - [n/a - n/a - n/a])	ICSR
EU-EC- 10010951038	14/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - ), COVID-19 (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved - ), Dizziness (6d -			
										Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (6d - Recovered/Resolved - ), Groin pain (n/a -			
										Recovering/Resolving - ), Hunger (n/a -			
										Unknown - ),  Incoherent (1d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (5d - Recovered/Resolved - ),			
										Seizure (1d - Recovered/Resolved - Other Medically Important Condition),			
										Tremor (2h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010951040	14/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (8d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	FLUENZ TETRA [A/GUANGDONG- MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE STRAIN (A/HAWAII/66/2019, MEDI	ICSR
										Headache (n/a - Recovered/Resolved - Disabling),		326775), A/HONG KONG/2671/2019 (H3N2) - LIKE STRAIN (A/HONG KONG/2671/2019, MEDI 325078),	
										Inappropriate schedule of product administration (n/a - Unknown - ),		B/PHUKET/3073/2013 - LIKE STRAIN (B/PHUKET/3073/2013, MEDI 306444), B/WASHINGTON/02/2019 - LIKE STRAIN	
										Photophobia (n/a - Recovered/Resolved - Disabling)		(B/WASHINGTON/02/2019, MEDI 323797), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, MEDI	
												237514), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012	
												(YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751),	
												A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, MEDI 228029), B/BRISBANE/60/2008	
												(VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (G/BOLIVIA/559/2013, MEDI	
												(A/BOLIVIA/559/2013, MEDI 255962), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE	

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FILEC	14/12/2021	Sportaneous	Healthcare	Non	Not	12-17	Not	Female	No	Perinheral swelling	COMIDNATY (TOZINAMERAN)	STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/NEW CALEDONIA/71/2014, MEDI 263122), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/MICHIGAN/45/2015 (H1N1)PDM09 - LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16-0019/2016, MEDI 291690), B/COLORADO/66/2017-LIKE STRAIN (B/COLORADO/66/2017-LIKE STRAIN (B/COLORADO/66/2017-LIKE STRAIN (B/COLORADO/66/2017-LIKE STRAIN (B/COLORADO/66/2017-LIKE STRAIN (B/COLORADO/66/2017-LIKE) STRAIN (B/COLORADO/66/2017-LIKE) MEDI 293454)] (C - n/a - n/a - n/a - n/a - n/a)	
EU-EC- 10010951047	14/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - Disabling), Platelet count decreased (n/a - Unknown - Disabling), Skin discolouration (n/a - Unknown - Disabling), Thrombosis (n/a - Unknown - Disabling, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010951405	14/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Important Condition) Fatigue (2d - Recovered/Resolved - ), Lymphadenopathy (n/a - Recovering/Resolving - ), Pain in extremity (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010951587	14/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Tachycardia (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010951743	14/12/2021	Spontaneous			Not available		Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not		Not reported	ICSR

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										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pallor (n/a - Unknown - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010951840	14/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CODEINE] (C - n/a - n/a - [30d - n/a - n/a]), [DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM] (C - n/a - n/a - [30d - n/a - n/a]),	<u>IC</u>
										Blood urine present (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),		[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
										Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Muscle swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Protein urine present (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Rash (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10010951847	14/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pallor (n/a - Unknown - ), Unresponsive to stimuli (0d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [MESTRANOL, NORETHISTERONE] (S - n/a -	Not reported	IC
EU-EC- 10010951934	14/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No		Unknown - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	IC
EU-EC- 10010951949	14/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Chest pain (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
										Electrocardiogram ST segment elevation (594h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			

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		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (27d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (594h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (27d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Systolic dysfunction (594h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin I increased (594h - Recovered/Resolved - Caused/Prolonged Hospitalisation) Acute stress disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10010951972 EU-EC-		Spontaneous	Professional Healthcare	Economic Area Non	Not available	12-17	Not Specified	Male Male	No No	Pyrexia (n/a - Recovering/Resolving - ), Tension (n/a - Recovering/Resolving - ), Tremor (17min - Recovered/Resolved - ) Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Condition aggravated	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN]		<u>IC</u>
10010951977			Professional	European Economic Area	available	Years	Specified			(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - ), Orthostatic intolerance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - )			
EU-EC- 10010951990	14/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Chest discomfort	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	I

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											Caused/Prolonged Hospitalisation),			
											Myocarditis (n/a - Unknown -			
											Caused/Prolonged Hospitalisation,			
											Other Medically Important Condition),			
											Off label use (n/a - Unknown - ),			
											Overdose (n/a - Unknown - )			
	EU-EC- 10010952213	14/12/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Cerebrovascular accident (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
				Professional	Economic Area						Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
											Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Headache (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Photophobia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Sleep paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Vision blurred (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
	511.50						12.47				Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			TOOD
	EU-EC- 10010952371	14/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Pain in extremity (n/a - Recovered/Resolved - Other Medically			
	EU-EC- 10010952476	14/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Menometrorrhagia (n/a - Not	COMIRNATY [TOZINAMERAN]	ZONISAMIDE MYLAN 50 MG HARD CAPSULES [ZONISAMIDE]	ICSR
	10010332170			Professional		available	lcuis				Recovered/Not Resolved - )	n/a - [1d3mL - Intramuscular])	(C - n/a - n/a - [n/a - n/a - n/a])	
	EU-EC- 10010952520	14/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Professional	Area						Resolved - ), Intermenstrual	Not applicable - [1d3mL - Intramuscular])		
											bleeding (n/a - Not Recovered/Not			
	EU-EC- 10010952561	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved - ) Herpes zoster (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
	EU-EC-	14/12/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No		Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	10010952571			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved - )	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
	EU-EC- 10010952593	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved - ), Vomiting (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
-	FIL FC	14/10/22	C	N	F	N-4	12.1-	A	N4-1		Recovered/Resolved	COMPNIATY	N.A	100=
	EU-EC- 10010952599	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	ıশdl€	No	Asthma (n/a - Recovering/Resolving - ), Immunisation reaction (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
											Recovering/Resolving			
	EU-EC- 10010952602	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (4d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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										Influenza like illness (4d - Recovered/Resolved - )	Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010952721	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eye disorder (15h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
										Eye pain (15h - Recovered/Resolved - ),			
										Influenza like illness (15h - Recovered/Resolved - )			
EU-EC- 10010952725	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Chest pain (n/a - Recovering/Resolving - ), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Recovering/Resolving - ), Influenza like illness			
										(n/a - Recovering/Resolving - ), Tachycardia (n/a -			
										Recovering/Resolving			
EU-EC- 10010952729	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Recovered/Resolved - ), Chest pain (5d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSR
										- ), Influenza like illness (n/a -			
										Recovered/Resolved - ),			
										Lymphadenopathy (n/a - Recovered/Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Palpitations (n/a - Recovered/Resolved - ),			
										Tinnitus (n/a - Recovered/Resolved - )			
EU-EC- 10010953297	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Acute generalised exanthematous pustulosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Drug reaction with eosinophilia and systemic symptoms (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Multisystem			
										inflammatory syndrome in children (n/a - Recovering/Resolving			
EU-EC- 10010953631	14/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	- Life Threatening) Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
10010933031			Professional		available	leais	Specified			- ), Fatigue (n/a - Not Recovered/Not Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Injection site swelling (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Recovering/Resolving - ),			
EU-EC-	14/12/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - ) Malaise (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010953780			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - ), Muscular weakness (n/a - Not	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Not Resolved - ),			

EU-EC-										Torus fracture (n/a - Not Recovered/Not			
			1							Resolved - Other Medically Important Condition)			
1001095379		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001095402		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Acute flaccid myelitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 100109541		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001095420		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (4d - Recovering/Resolving - ), Vomiting (4d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001095429		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Fatigue (0d - Not Recovered/Not Resolved - ), Influenza (0d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Unknown - ), Pyrexia (0d - Not Recovered/Not Resolved - )			
EU-EC- 1001095462		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (30min - Not Recovered/Not Resolved - ), Syncope (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 1001095516		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tension headache (n/a - Recovered/Resolved - ), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU 50	14/12/2021	Constant	1114		N	12.17	A d . l	F1-	NI-	Recovered/Resolved	COMPONENT STOTINGAMED AND	Networked	Teen
EU-EC- 1001095600		Spontaneous	Professional		Not available	12-17 Years	Adolescent	remaie	No	Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC-	14/12/2021	Spontaneous	Haaltheara	Europoan	Not	12 17	Adolescent	Fomale	No	Syncope (0d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN]	Not reported	ICCD
100109560		Spontaneous	Professional	European Economic Area	available	12-17 Years	Adolescent	remale	INO	(n/a - Unknown - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										Unknown - Caused/Prolonged Hospitalisation),			
										Illness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Inflammation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Iridocyclitis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Kawasaki's disease (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Mouth ulceration (n/a - Unknown - Caused/Prolonged Hospitalisation),			
EU-EC- 100109560		Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)  Menstrual disorder (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	[ETHINYLESTRADIOL, LEVONORGESTREL] (C -	ICSR
				Area						Recovered/Not Resolved - ), Vaginal haemorrhage	Not applicable - [n/a - 1{DF} - n/a])	Contraception - n/a - [n/a - n/a - Oral])	
EU-EC-	14/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	(n/a - Not Recovered/Not Resolved - ) Headache (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

0010956151			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved - )	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -		
U-EC- 0010956185	14/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymph node pain (n/a - Not Recovered/Not Resolved - ), Vaccination site lymphadenopathy	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	IC
	14/12/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	(n/a - Not Recovered/Not Resolved - ) Muscular weakness	COMIRNATY [TOZINAMERAN]	Not reported	IC
0010956198			Healthcare Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not	(S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		
	14/12/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Recovered/Not Resolved - ) Lymph node pain	COMIRNATY [TOZINAMERAN]	Not reported	IC
0010956211			Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
U-EC- 0010956231	14/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Not Resolved - ) Pyrexia (99d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	IC
U-EC- 0010956239	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Influenza (n/a - Recovering/Resolving - )	Intramuscular]) COMIRNATY [TOZINAMERAN]	[TETRACYCLINE, TETRACYCLINE HYDROCHLORIDE] (C - Acne - n/a - [n/a - n/a])	<u>I</u>
0010956291		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		10
J-EC- 0010956327	14/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	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	10
										(n/a - Unknown - Other Medically Important Condition)			
U-EC- 0010932384	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (3d - Recovered/Resolved - )	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]	Not reported	I
U-EC- 0010932604	13/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition),		[LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEBEVERINE] (C - n/a - n/a - [n/a - n/a - n/a]),	Ī
										Chest pain (n/a - Unknown - Other Medically Important Condition),		[OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Decreased appetite (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Loss of personal independence in daily activities (n/a - Unknown - 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),				
										Nausea (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			

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										Swelling (n/a - Unknown - Other Medically Important Condition)			
:U-EC- 0010932710	13/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a])	IC
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Unknown - Other Medically Important Condition),			
1.50	42/42/2024		Mari	Non	Note	12.17	Note	- I	N	Sensation of foreign body (n/a - Unknown - Other Medically Important Condition)	COMPANY (FROTHAMEDAN)		
0010932729		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
J-EC- 0010933088	13/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Unknown - ), Pain (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										- ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a -			
J-EC-	13/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Unknown - ) Embolism (n/a -	FLUENZ TETRA	Not reported	+
0010933300	10,11,1011	<b>Gportaliso</b>	Professional	European Economic Area	available	Years	Specified			Unknown - Caused/Prolonged Hospitalisation, Other Medically Important	[A/GUANGDONG- MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE STRAIN (A/HAWAII/66/2019, MEDI 326775), A/HONG		
								Condition),  Epistaxis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	KONG/2671/2019 (H3N2) - LIKE STRAIN (A/HONG KONG/2671/2019, MEDI 325078), B/PHUKET/3073/2013 - LIKE STRAIN				
								Epistaxis (n/a - Unknown - Caused/Prolonged Hospitalisation),	(B/PHUKET/3073/2013, MEDI 306444), B/WASHINGTON/02/2019 - LIKE STRAIN (B/WASHINGTON/02/2019,				
										Haematuria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	MEDI 323797), A/TEXAS/50/2012 (H3N2)- LIKE STRAIN (A/TEXAS/50/2012, MEDI 237514), PRINCEANE (60/2008)		
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012		
										Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	(YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/CALIFORNIA/7/2009		
										Hypotension (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	(H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, MEDI 228029), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE		
										Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation),	STRAIN (B/BRISBANE/60/2008, MEDI 228030), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/BOLIVIA/559/2013, MEDI		
										Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved	255962), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI		
										- Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved	254977), A/HONG KONG/4801/2014 (H3N2)- LIKE STRAIN (A/NEW CALEDONIA/71/2014, MEDI 263122),		
									<ul> <li>Caused/Prolonged Hospitalisation),</li> <li>Myocarditis (n/a - Recovered/Resolved</li> <li>Caused/Prolonged</li> </ul>	B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/MICHIGAN/45/2015			
										Hospitalisation, Other Medically Important Condition),	(H1N1)PDM09 - LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16- 0019/2016 (H3N2)-LIKE		
										Neck pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Oropharyngeal pain	STRAIN (A/SINGAPORE/INFIMH-16- 0019/2016, MEDI 291690), B/COLORADO/06/2017-LIKE STRAIN (B/COLORADO/06/2017,		
										(n/a -	MEDI 293454),		-1

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										- Caused/Prolonged Hospitalisation), Pharyngeal swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pulse abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash maculo-papular (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged - Ca	B/PHUKET/3073/2013 - LIKE STRAIN (B/PHUKET/3073/2013, MEDI 306444), B/WASHINGTON/02/2019 - LIKE STRAIN (B/WASHINGTON/02/2019, MEDI 323797), A/CAMBODIA/E0826360/2020 (H3N2) - LIKE STRAIN (A/TASMANIA/503/2020, MEDI 339018), A/VICTORIA/2570/2019 (H1N1)PDM9 - LIKE STRAIN (A/VICTORIA/1/2020, MEDI 340505)] (S - Influenza immunisation - Not applicable - [1d - n/a - Nasal]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010933385	13/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Headache (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[SOMATROPIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010933400	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Cough variant asthma (n/a - Recovering/Resolving - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010933413	13/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010934232	13/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Urticaria (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010934301	13/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Pyrexia (12h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010934349	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (n/a - Unknown - Other Medically Important Condition), Oral herpes (n/a - Unknown - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010934367	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Sleep disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

								Cull Li				
									- Other Medically			
13/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved	(S - COVID-19 immunisation -	Not reported	IC:
		Torcasional	Area						Headache (n/a - Recovered/Resolved	n/a])		
									Myalgia (n/a - Recovered/Resolved			
									Nausea (n/a - Recovered/Resolved			
13/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved - ),	FOR DISPERSION FOR INJECTION COVID-19 MRNA	Not reported	IC
									Dizziness (n/a - Not Recovered/Not Resolved - ),	MODIFIED) [TOZINAMERAN]   (S - COVID-19 immunisation -   Not applicable - [n/a - n/a -		
									Dysphoria (n/a - Not Recovered/Not Resolved - ),	17-20		
									Ear pain (n/a - Not Recovered/Not Resolved - ),			
									Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),			
									Pulse abnormal (n/a - Not Recovered/Not Resolved - ),			
									Pyrexia (n/a - Recovered/Resolved - )			
13/12/2021	Spontaneous			Not available		Not Specified	Male	No	decreased (0d - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	IC
									Feeling abnormal (n/a - Recovered/Resolved - ),			
									Headache (n/a - Recovered/Resolved - ),			
									Presyncope (n/a - Recovered/Resolved - )			
13/12/2021		Healthcare	Non European Economic Area	Not available			Male	No	Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
									Nasopharyngitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
									Pain (n/a - Unknown - Other Medically Important Condition),			
									Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition).			
									Syncope (n/a - Recovered/Resolved - Other Medically			
13/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
									Headache (3d - Recovered/Resolved - Other Medically Important Condition),			
									Myalgia (1d - Recovered/Resolved - Other Medically Important Condition),			
									Vaccination site pain			
	13/12/2021	13/12/2021 Spontaneous  13/12/2021 Spontaneous  13/12/2021 Spontaneous	13/12/2021 Spontaneous Healthcare Professional  13/12/2021 Spontaneous Healthcare Professional  13/12/2021 Spontaneous Non Healthcare Professional	Healthcare Professional In Indiana Ind	Healthcare Professional I Sconomic Area I Surgean Reconomic Area I Surg	Healthcare Professional Area  13/12/2021 Spontaneous Healthcare Professional Realthcare Realthcare Professional Realthcare Professional Realthcare Realthcare Professional Realthcare	Healthcare Professional Area  13/12/2021 Spontaneous Healthcare Professional Economic Area  13/12/2021 Spontaneous Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare European Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Economic Area  13/12/2021 Spontaneous Non Healthcare Professional Professional Professional Professional Professiona	Healthcare Professional Area    Healthcare Professional Area   Professional Area   Professional Area   Professional Area	Healthcare Professional Area    Healthcare Professional Area   European Not Area   Healthcare Professional European Not Area   13/12/2021   Spontaneous Professional European Not Professional European Not Professional European Not Professional European Not Professional European Not Professional European Not Professional European Not Professional European Not Professional European Not Professional European Not Not Not Not Not Not Not Not Not Not	13/12/2021 Sportlaneous   Non- Professional   Area   Non- Professional   Non- Professiona	13/13/2021   Southweek   Professional   Professio	2011/2021   Special words   Nature   Section   Na

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										With Sequelae - Other Medically Important Condition)			
:U-EC- 0010934725	13/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	IC
				Area						Diarrhoea (n/a - Unknown - ),	Intramuscular])		
										Feeling abnormal (1d			
										Recovered/Resolved - ),			
										Loss of consciousness (1d - Recovered/Resolved			
U-EC-	13/12/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	- Other Medically Important Condition) Dizziness (n/a - Not	COMIRNATY [TOZINAMERAN]	[SERTRALINE SERTRALINE	1
0010934741	10, 11, 1011	oponianosas		Economic	available	Years	Specified			Recovered/Not Resolved - ),		HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - n/a])	
										Feeling abnormal (n/a - Not Recovered/Not Resolved - ),	1,14,1		
										Inappropriate schedule of product administration (n/a - Unknown - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
								Vaccination site discolouration (n/a - Not Recovered/Not Resolved - ),					
								Vaccination site pain (n/a - Not Recovered/Not Resolved - ),					
								Vaccination site swelling (n/a - Not Recovered/Not Resolved - )					
	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - ),		NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),		
		rocssona	Arcu						Headache (n/a - Not Recovered/Not Resolved - ),	- n/a])	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])		
								Injection site pain (n/a - Not Recovered/Not Resolved - )					
J-EC- 0010935480	13/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
										Chills (n/a - Not Recovered/Not Resolved - ),			
										Decreased appetite (n/a - Not Recovered/Not Resolved - ),			
										Dizziness (n/a - Not Recovered/Not Resolved - ),			
										Eye pain (n/a - Not Recovered/Not Resolved - ),			
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Heart rate increased (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site pain (n/a - Not			

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EU-EC-	13/12/2021	Spontaneous		European	Not		Not	Male	No	Resolved - ) Facial paralysis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	IC
L0010935556 EU-EC-	13/12/2021	Spontaneous	Professional	Economic Area European	available Not	Years 12-17	Specified Not	Male	No		(S - n/a - n/a - [n/a - n/a - n/a])  COMIRNATY [TOZINAMERAN]	[RISPERIDONE] (C - n/a - n/a -	IC
10010935879	15/12/2021	эропшисоцз	Healthcare	Economic Area	available		Specified	ridic			(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	[n/a - n/a - n/a]),	1
										Headache (n/a - Not Recovered/Not Resolved - ),	- n/a])	[SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
J-EC- 0010936334	13/12/2021	Spontaneous		European Economic Area	Not available		Not Specified	Female	No	- Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	]
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
									Gait inability (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),				
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
U.E.C.	12/12/2021	Contract	Non	Europa	Not	12.47	Not	Eore-1	Ne	Vertigo (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COMIDNATY FROTUNG	Not reported	
U-EC- 0010936572	13/12/2021	Spontaneous			Not available		Not Specified	Female	No	Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	
										Menstruation			

			l	I	I	1	l	I	I	irregular (n/a - Not	I		1
										Recovered/Not Resolved - )			
:U-EC- .0010936586	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Menstrual disorder (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		IC
U-EC-	12/12/2021	Cnantanagus	Non	Europoon	Not	12-17	Not	Male	No	Recovered/Not Resolved - )	COMIDNATY FTOZINAMEDANI	DUTAMIN DI (C. p/o. p/o. fp/o.	10
.0010936587	13/12/2021	Spontaneous		European Economic Area	Not available	Years	Not Specified	Male	INO	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Musculoskeletal	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ı <u>IC</u>
										stiffness (n/a - Not Recovered/Not Resolved - ), Pain in extremity			
										(n/a - Not Recovered/Not Resolved - )			
U-EC- 0010936588	13/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - Disabling), Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	IC
										Unknown - Disabling)			
EU-EC- 10010936591	13/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - ), Gingival bleeding (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	IC
										Incomplete course of vaccination (n/a - Unknown - ),			
										Vaccine breakthrough infection (n/a - Unknown - Other Medically Important			
EU-EC- 10010936621	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition)  Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	IC
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
EU-EC-	12/12/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN]	ANTICONCEDITEDI. INOT	IC
10010936655	13/12/2021			Economic	available	Years	Specified	remale	INO	bleeding (n/a - Not Recovered/Not Resolved - ),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	- 1
										bleeding (n/a - Not Recovered/Not Resolved - )			
10010936666			Healthcare Professional	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])		<u>IC</u>
EU-EC- .0010936670	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	10
										Chills (1d - Recovered/Resolved -), Extensive swelling of			
										vaccinated limb (n/a - Not Recovered/Not Resolved - ),			
										Fatigue (1d - Recovered/Resolved - ),			
										Headache (1d - Recovered/Resolved -), Injection site			
										erythema (n/a - Not Recovered/Not Resolved - ), Injection site pain			
										(n/a - Not Recovered/Not			
										Resolved - ), Injection site			

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										Resolved - ), Injection site warmth (n/a - Not Recovered/Not			
										Resolved - ),  Malaise (2d - Recovered/Resolved			
EU-EC- 10010936671	13/12/2021	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])	Not reported	ICSR
										Myalgia (n/a - Recovering/Resolving - )			
EU-EC- 10010936804	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Dyskinesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Movement disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	13/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Abdominal pain	COMIRNATY CONCENTRATE	Not reported	ICSR
10010936822	13/12/2021	Sportaneous	Professional		available	Years	Specified	remale	NO	upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSK
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of	Intramuscular])		
										consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010936943	13/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotonic- hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - [n/a - n/a - [ntramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	madinascalar ()		
	10.110.11					15				Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010937426	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Recovering/Resolving - ), Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - )			
EU-EC-	13/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Chills (4h -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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10010937449			Healthcare Professional		available	Years				Recovered/Resolved - ),	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])		
										Headache (4h - Recovered/Resolved - ),			
										Pyrexia (4h - Recovered/Resolved - )			
EU-EC- 10010937458	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (0d - Recovered/Resolved - ),			
										Feeling hot (1d - Recovered/Resolved - ),			
										Headache (1d - Recovered/Resolved - ),			
										Influenza (0d - Recovered/Resolved - ),			
										Injection site pain (2d - Recovered/Resolved			
										Myalgia (0d - Recovered/Resolved			
										Pyrexia (1d - Recovered/Resolved			
EU-EC- 10010937651	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site reaction (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010937754	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not	Not reported	ICSR
										Dysphagia (2d - Recovering/Resolving - ),	otherwise specified)])		
										Dyspnoea (2d - Recovering/Resolving - ),			
										Injection site swelling (6d - Recovered/Resolved			
										Throat irritation (2d - Recovering/Resolving			
EU-EC- 10010938302	13/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Genital herpes (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Hospitalisation),  Genital pain (n/a - Unknown -			
EU-EC-	13/12/2021	Spontaneous		European	Not	12-17	Not	Female	No	Caused/Prolonged Hospitalisation) Fatigue (3d -		Not reported	<u>ICSR</u>
10010938373			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved - ), Headache (3d -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Recovered/Resolved - ), Myalgia (3d -			
EU-EC-	13/12/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Recovered/Resolved - ) Epistaxis (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010938630	15,12,2021	эропштова	Healthcare Professional	European	available	Years	Specified	- ciriale		Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010938635	13/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Condition),  Nausea (n/a - Unknown - Other Medically Important			
										Condition), Pyrexia (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10010938652	13/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Important Condition) Headache (n/a - Not Recovered/Not Resolved - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	<u>ICSR</u>
				Area						Condition),	n/a])		

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EU-EC- 10010938658	12/2021 S <sub>I</sub>		Healthcare	Not available		Not Specified	Female	No	Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
									Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Feeling of body temperature change (n/a - Unknown - Other Medically Important Condition),  Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010938662	12/2021 Sp	pontaneous	Healthcare	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
									Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ),			
									Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not			
									Recovered/Not Resolved - ),  Vaccination site pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010938671	12/2021 S <sub>I</sub>	pontaneous		Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - ), Chest pain (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition))	COMINATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN (A/BRISBANE/59/2007 REASS. IVR-148), A/BRISBANE/10/2007 (H3N2)-LIKE STRAIN (A/URUGUAY/716/2007 REASS. NYMC X-175C), B/BRISBANE/60/2008-LIKE VIRUS, A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN (A/BRISBANE/59/2007 REASS. IVR-148), A/BRISBANE/59/2007 REASS. IVR-148), A/BRISBANE/59/2007 REASS. IVR-148), A/BRISBANE/59/2007 REASS. IVR-148), A/BRISBANE/59/2007 REASS. IVR-148), A/BRISBANE/10/2007 REASS. IVR-148), A/BRISBANE/10/2007 REASS. NYMC X-175C), B/FLORIDA/4/2006-LIKE STRAIN (A/URUGUAY/116/2007 REASS. NYMC X-175C), B/FLORIDA/4/2006-LIKE STRAIN (B/FLORIDA/4/2006-LIKE STRAIN (B/FLORIDA/4/2009) (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR- 116), B/MALAYSIA/2506/2004 - LIKE STRAIN (A/HIROSHIMA/52/2005 REASS. IVR-142), ANTIGENS OF THE INFLUENZA VIRUS A/CALIFORNIA/7/2009 (H1N1)- LIKE VIRUS, ANTIGENS OF THE INFLUENZA VIRUS A/VICTORIA/361/2011 (H3N2)- LIKE VIRUS, ANTIGENS OF THE INFLUENZA VIRUS B/WISCONSIN/1/2010-LIKE VIRUS, B/BRISBANE/60/2009- LIKE VIRUS, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)- DERIVED STRAIN USED NYMC X- 181, B/MALAYSIA/2506/2004 - LIKE STRAIN (B/MALAYSIA/2506/2004), A/WISCONSIN/67/2005 (H3N2) - LIKE STRAIN (B/MALAYSIA/2506/2004), A/WISCONSIN/67/2005 (R4SS.) NYMC X-187), A/CALIFORNIA/7/2009 (H3N2) - LIKE STRAIN (B/MALAYSIA/2506/2004), A/WISCONSIN/67/2005 (R4SS.) NYMC X-187), A/CALIFORNIA/7/2009 (H3N2) - LIKE STRAIN (B/MALAYSIA/2506/2004), A/WISCONSIN/67/2005 (R4SS.) NYMC X-187), A/CALIFORNIA/7/2005 (R4SS.)	

													,
										Malaise (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Muscle spasms (965min - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Myoclonic epilepsy (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Neuritis cranial (965min - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Postictal paralysis (965min - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Seizure (965min - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
:U-EC- .0010938764	13/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	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	ICS
										Bradycardia (n/a - Unknown - Other Medically Important Condition),			
EU-EC- 10010938791	13/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - ) Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
U-EC- 0010938798	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myocarditis (3030min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically			
	13/12/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Product use issue (n/a - Unknown - Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	ICS
EU-EC- 10010938806			Professional	Area						Other Medically Important Condition),			

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										- Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010938885	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not			
EU-EC- 10010938940	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - )  Condition aggravated (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]),	Not reported	ICSR
										Depressed mood (0d - Recovered/Resolved - ),	[IVERMECTIN] (S - Acarodermatitis - Not applicable - [n/a - n/a - Oral]),		
										Headache (1d - Recovered/Resolved - ),	[PERMETHRIN] (S - Acarodermatitis - n/a - [8d - n/a - Cutaneous])		
										Off label use (0d - Unknown - )			
EU-EC- 10010939074	13/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Polymenorrhoea (n/a			
										Recovering/Resolving - )			
EU-EC- 10010939098	13/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010939129		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Angina pectoris (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])		ICSR
EU-EC- 10010939140		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Menometrorrhagia (n/a - Not Recovered/Not Resolved - )	(S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010939366	13/12/2021	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 - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010939459	13/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Aphthous ulcer (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										Erythema (n/a - Not Recovered/Not Resolved - ),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010939492	13/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Facial paralysis (3wk - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC-	13/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	- ) Anxiety (n/a - Not	Intramuscular])	Not reported	ICSR
10010939494		·	Professional		available	Years				Recovered/Not Resolved - ), Chest pain (n/a - Not	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	·	
										Recovered/Not Resolved - ), Dyspnoea (n/a - Not			
										Recovered/Not Resolved - )			
EU-EC- 10010939519		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	-)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010939548		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Immunisation reaction (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10010939639		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	(n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])		ICSR
EU-EC- 10010939712	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (6d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010939714	13/12/2021	Spontaneous	Non 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 - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010939798	13/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (6d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a]),	Not reported	ICSR

U-EC-	13/13/303	Spontaneous	Non	Europes -	Not	12 17	Net	Female	No	Hoadasho (a/a Na	[MENINGOCOCCAL GROUP B VACCINE] (S - n/a - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	IC
0010939828	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	remaie	INO	Headache (n/a - Not Recovered/Not Resolved - ),	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	10
										Nausea (n/a - Not Recovered/Not Resolved - ),			
L FC	12/12/2021	Chantanaous	Llooithoore	Non	Not	12 17	Not	Mala	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN]	Not reported	I
U-EC- 0010939914	13/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	(3h - Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	1
										Cold sweat (3h - Recovered/Resolved - ),			
										Feeling hot (3h - Recovered/Resolved - ),			
										Nausea (3h - Recovered/Resolved - ),			
										Pallor (3h - Recovered/Resolved - ),			
										Rash (3h - Recovered/Resolved - )			
0010939920		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
J-EC- 0010939926	13/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
	12/12/2021					12.17				Vaccination site swelling (n/a - Recovering/Resolving - Other Medically Important Condition)			
J-EC- 0010939941	13/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Neuralgia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a -			

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										Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10010940187		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Haematoma (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Immune thrombocytopenia (2d - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10010940220		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Hepatic failure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Pancreatitis acute (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 1001094022		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010940252	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Apathy (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])		ICSR
										Confusional state (n/a - Recovering/Resolving - Other Medically Important Condition),		[SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	
										Decreased appetite (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Eye disorder (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Influenza like illness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Sleep disorder (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010940297		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (4d - Recovering/Resolving - Other Medically Important Condition),		[ETHINYLESTRADIOL, LEVONORGESTREL, PLACEBO] (C - Contraception - n/a - [n/a - 1{DF} - Oral])	ICSR
										Oedema peripheral (5d - Recovered/Resolved - Other Medically Important Condition),			
										Pruritus (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash maculo-papular			
								[					

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										(5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010940311	13/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Influenza like illness (n/a - Not Recovered/Not Resolved - ),			
										Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010940380	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010940382	13/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Erythema (13d - Not Recovered/Not Resolved - )		Not reported	ICSR
EU-EC- 10010940390	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1d - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010940395	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (29d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010940417		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	Not applicable - [22d - 1{DF} - Intramuscular])	[BILASTINE] (C - n/a - n/a - ), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a])	ICSR
EU-EC- 10010940460	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010940474	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (n/a - Recovering/Resolving -),	(S - Immunisation - n/a - [n/a	Not reported	ICSR
										Menstrual disorder (n/a - Recovering/Resolving - )			
EU-EC- 10010940490	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010940493	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (1d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (1d - Recovered/Resolved - ), Headache (1d -			
										Recovered/Resolved - ), Influenza (1d - Recovered/Resolved			
										- ), Injection site pain			
										(2d - Recovering/Resolving - ),			
EU 50	12/12/2021	Constant	New	F	N	12.17	a d. It.		N.	Pyrexia (1d - Recovered/Resolved - )	COMPNAD/ FTOTMAMED AND	No.	Teen
EU-EC- 10010940495	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Influenza like illness (n/a - Unknown - ), SARS-CoV-2 test positive (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown - ),  Vaccination failure (n/a - Unknown - )			
EU-EC- 10010940507	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010940509	13/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (4d - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010940524	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Recovered/Resolved - ),			
										Injection site pain (n/a - Recovered/Resolved -)			
EU-EC-	13/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Chills (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10010940526			Healthcare Professional		available	Years				Recovered/Resolved - ), Chills (2d - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										- ), Fatigue (2d - Recovered/Resolved - ),			
										Headache (0d - Recovered/Resolved - ),			
										Injection site pain (2d - Recovered/Resolved			
										Limb discomfort (1d			
										- Recovered/Resolved			
										- ), Oedema (10d -			
										Recovered/Resolved - ),			
										Paraesthesia (1d - Recovered/Resolved - ),			
										Pyrexia (2d - Recovered/Resolved - )			
EU-EC- 10010940527		Spontaneous Spontaneous	Healthcare Professional	1	Not available	12-17 Years	Adolescent  Adolescent		No No	Menstrual disorder (n/a - Unknown - ) Dizziness (0d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]		ICSR
10010940531	13/12/2021	Spontaneous		European Economic Area	available	Years	Adolescent	Мане	INO	Recovered/Not Resolved - )	(S - Immunisation - n/a - [n/a  - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010940533	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Circulatory collapse (0d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC-	13/12/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Important Condition) Syncope (0d - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010940537			Professional		available	Years				Recovered/Not Resolved - Other Medically Important Condition)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010940569	13/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010940882	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	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
EU-EC- 10010940883	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (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
										Dizziness postural (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Heart rate increased (n/a - Not Recovered/Not Resolved - ),			
										Orthostatic hypotension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Orthostatic intolerance (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010940885	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Defect conduction intraventricular (n/a - Unknown - Other Medically Important Condition),	-		
										Diarrhoea (4d - Recovered/Resolved - ), Dizziness (n/a - Not			
										Recovered/Not Resolved - ),			

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										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Physical deconditioning (n/a - Unknown - ),			
										Pyrexia (4d - Recovered/Resolved			
EU-EC- 10010940891	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (690min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Aphasia (690min - Recovered/Resolved - Other Medically Important Condition),			
										Blood pressure decreased (690min - Recovered/Resolved - Other Medically Important Condition),			
										Chills (690min - Recovered/Resolved - Other Medically Important Condition),			
										Fall (690min - Recovered/Resolved - Other Medically Important Condition),			
										Feeling cold (690min			
										Recovered/Resolved - Other Medically Important Condition),			
										Oxygen saturation abnormal (690min - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (690min - Recovered/Resolved - Other Medically Important Condition),			
										Supine position (690min - Recovered/Resolved - Other Medically			
EU-EC- 10010940898	13/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Carditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Chest pain (n/a - Not Recovered/Not Resolved - ),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010940943	13/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Urticaria (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010941580	13/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness neurosensory (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Dysacusis (n/a - Unknown - ), Headache (n/a -			
										Unknown - ), Pyrexia (n/a -			
		1		I	1	1	1	1	I	Unknown - )	I.		- 1

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EU-EC- 10010941878	13/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]  (S - n/a - n/a - [n/a - n/a -  n/a])	Not reported	ICSF
EU-EC- 10010942048	13/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (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	ICSF
										Bone pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Toothache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010943394	13/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gastroenteritis (2d - Recovered/Resolved - ), Pyrexia (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010943750	13/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved - ) Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSI
EU-EC- 10010931892	12/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	- n/a])  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- 10010931896	12/12/2021	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	ICSF
EU-EC-	12/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSI
10010931923	,,		Professional		available	Years				Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010932083	12/12/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Male	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a		ICSI
			Professional	Area						Resolved - Caused/Prolonged Hospitalisation)	- n/a - n/a])		

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EU-EC- 10010932215	12/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010932239	12/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010932328	12/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010929167	11/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pancytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
										Thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010929169	11/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cerebral ischaemia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010929332	11/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Face oedema (0d - Recovered/Resolved - ), Tongue oedema (0d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10010929720	11/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Epilepsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010929866	11/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (5h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Dysmenorrhoea (n/a - Recovering/Resolving -),			
										Malaise (5h - Recovered/Resolved - )			
EU-EC- 10010929892	11/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	<del>- '</del>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving			
										- ), Headache (n/a - Not Recovered/Not Resolved - ),			
										Hyperpyrexia (n/a - Recovering/Resolving - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Recovering/Resolving - ), Nausea (n/a -			
EU-EC- 10010929894	11/12/2021	Spontaneous	Non Hea <b>l</b> thcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovering/Resolving -) Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional							- ), Headache (3d - Recovered/Resolved	Not applicable - [n/a - 1{DF} - n/a])		
										- ), Malaise (3d - Recovered/Resolved - ),			
										Pyrexia (3d - Recovered/Resolved - ),			
										Tachycardia (n/a - Recovering/Resolving - )			
EU-EC- 10010929928	11/12/2021	Spontaneous	Non Hea <b>l</b> thcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>

			Professional	Area						Recovered/Not Resolved - )	Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010929958	11/12/2021	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 - 1{DF}	Not reported	IC
EU-EC- 10010930096	11/12/2021	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 - ),	- n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	IC
										Menstruation delayed (n/a - Not Recovered/Not Resolved - ),			
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010931404	11/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	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	]
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010912492	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Tachycardia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	
EU-EC- 10010912810	10/12/2021	Spontaneous	Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	1
EU-EC- 10010913082	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haematemesis (n/a - Recovering/Resolving - Life Threatening),	COMIRNATY [TOZINAMERAN]	[PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]),	]
										Oesophageal varices haemorrhage (n/a - Recovering/Resolving - Life Threatening)	,	[TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - Liver transplant - n/a - [n/a - 3mg - Oral]),	
												[URSODEOXYCHOLIC ACID] (C - Congenital absence of bill ducts -	
EU-EC- 10010913084	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	n/a - [n/a - 600mg - Oral]) Not reported	
										N-terminal prohormone brain natriuretic peptide increased (n/a - Unknown - Caused/Prolonged Hospitalisation),	,		
										Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010913086	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	
EU-EC- 10010913534		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC- 10010913566	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC- 10010913576	10/12/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010913596	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC- 10010913605	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	•
										Ewing's sarcoma (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pleural effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			

1		l	1	1						Scolincie (n/a -			
U-EC-	10/12/2021	Casatassassa	I I a a libba a a a a	Nam	Net	12.17	Nat	Mala	Na	Scoliosis (n/a - Unknown - )	COMTRAINTY STOZINAMERANI	Not were stand	4
0010913612	10/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	1
										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),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
J-EC- 0010913615	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	ARIPIPRAZOLE [ARIPIPRAZOLE] (C - Depression - n/a - [n/a - n/a - n/a]),	
										Condition),  Muscle spasms (n/a - Recovered/Resolved - Other Medically Important Condition),		MELATONIN [MELATONIN] (C - Nightmare - n/a - [n/a - n/a - n/a]),  [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Palpitations	
										Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition),		- n/a - [n/a - n/a - n/a])	
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Polyuria (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition),			
										Visual acuity reduced (n/a - Recovered/Resolved - Other Medically Important Condition)			
J-EC- 0010913621	10/12/2021	Spontaneous	Hea <b>l</b> thcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										Burning sensation (n/a - Recovering/Resolving - Other Medically			
J-EC- 0010913631	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Drug eruption (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			

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											Erythema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Hypersensitivity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Pruritus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
	EU-EC- 10010913814	10/12/2021	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-EC- 10010913821	10/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac disorder (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Chest pain (n/a - Unknown - Other Medically Important Condition),			
											Pain (n/a - Unknown - Other Medically Important Condition),			
											Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10010913836	10/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Cold sweat (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Disorientation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Heart rate decreased (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Hypotension (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Seizure (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Syncope (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			
											Condition),			

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EU-EC- 10010913842	10/12/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
			rioressional	Area						Resolved - Other Medically Important Condition), Chest pain (n/a -	n/a])		
										Unknown - Other Medically Important Condition), Inappropriate			
										schedule of product administration (n/a - Unknown - )			
10010913847	10/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10010914475	10/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	[LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]),  [NITROFURANTOIN] (C - n/a - n/a - [n/a - n/a - n/a]),  [PREDNISOLONE] (C - n/a	
EU-EC- 10010914491	10/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haemorrhage (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[n/a - n/a - n/a]) Not reported	ICS
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010914524	10/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Abdominal pain upper (n/a - Unknown - Other Medically Important Condition),			
										Chest pain (n/a - Unknown - Other Medically Important Condition),			
										Diarrhoea (n/a - Unknown - Other Medically Important Condition), Headache (n/a -			
										Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other			
										Medically Important Condition), Vomiting (n/a - Unknown - Other			
EU-EC- 10010914529	10/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition)  Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Muscle spasms (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- L0010914579	10/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Axillary pain (n/a - Not Recovered/Not			

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										Resolved - Other Medically Important Condition),			
										Body temperature (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Muscle swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Spinal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
J-EC- 0010914921	10/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICS</u>
U-EC- 0010915176	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d3mL - Intramuscular])	Not reported	ICS
U-EC- 0010915224	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - ),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR	Not reported	ICS
										increased (n/a - Unknown - Life Threatening),	INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
										Papilloedema (n/a - Unknown - ), Visual impairment			
U-EC- 0010915305	10/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL, ETHINYLESTRADIOL, ETHINYLESTRADIOL PH. EUR., DESOGESTREL B.P.] (C - Contraception - n/a - [n/a - n/a - n/a]),	ICS
										Condition aggravated (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),		[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Acne - n/a - [n/a - n/a - n/a])	
										Dyspepsia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Gastrooesophageal reflux disease (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Recovered/Not Resolved - Disabling, Other Medically Important			
										Recovered/Not Resolved - Disabling, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important			

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											Important Condition), Oesophageal pain (n/a - Unknown - Disabling, Other Medically Important Condition),			
		10/12/2021					10.17	No.			Photophobia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			1000
	EU-EC- 10010915340	10/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male		Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Cardiac murmur (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Costochondritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
	EU-EC- 10010915341	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male		Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											(n/a - Unknown - Caused/Prolonged			

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EU-EC- 10010915345	10/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Cough (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010915429	10/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haemorrhage (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICS
										Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		[LYMECYCLINE] (C - n/a - n/a - [n/a - n/a - n/a], [SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Immune thrombocytopenia (n/a - Unknown - Other Medically Important Condition),			
										Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010915443	10/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Feeling hot (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010915612	10/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a -		Not reported	ICS
EU-EC- 10010915626	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Recovering/Resolving - ), Haemorrhage subcutaneous (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICS
10010915642		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC-	10/12/2021	Spontaneous	Non Hea <b>l</b> thcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Administration site pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS

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										Fatigue (24h - Recovered/Resolved - ), Headache (n/a -			
										Recovered/Resolved			
EU-EC- 10010915828	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cellulitis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Chest pain (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Lymphadenopathy (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010915863	10/12/2021	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	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010915871	10/12/2021	Spontaneous	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	ICSR
EU-EC-	10/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) Fatique (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010915932	10/12/2021	Spontaneous		Economic	available	Years	Adolescent	Temale	No	Recovered/Resolved - ), Headache (n/a -	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSN
										Recovered/Resolved - ), Oedema peripheral (n/a - Not			
										Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not			
										Resolved - ), Rash (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010916149	10/12/2021	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 - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovered/Not Resolved - ), Migraine with aura (1d -			
										Recovered/Resolved - ), Nausea (1d -			
EU-EC-	10/12/2021	Spontaneous	Haalthaara	European	Not	12-17	Adolescent	Comple	No	Recovered/Resolved - ) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10010916194	10/12/2021	Spontaneous	Professional		available	Years	Adolescent	Temale	INO	Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC-	10/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10010916207	10/ 12/2021	Sportanieous	Professional		available	Years	AUDICOLEI IL	, chale	140	Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])	Toported	1035
EU-EC-	10/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10010916220	, ., ., .	,	Professional		available	Years				Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])	, <u>-</u>	
EU-EC-	10/12/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	(n/a - Unknown - Other Medically Important Condition) Menstruation	COMIRNATY CONCENTRATE	Not reported	ICSF
10010916270			Healthcare Professional	Economic Area	available	Years				irregular (n/a - Not Recovered/Not Resolved - )	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation -		

ELLEC	10/12/2021	Coorter	Non	Europe : :	Not	12.17	Child	Mala	Ne	Abdominal	Not applicable - [n/a - n/a - n/a]	Not reported	10
EU-EC- 10010916325	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	IC:
										Diarrhoea (n/a - Not Recovered/Not Resolved - Disabling)			
:U-EC- .0010916542	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[DESOGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral])	IC
:U-EC- .0010916761	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (1d - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN]	Not reported	10
										Meningitis aseptic (1d - Unknown - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
EU-EC- 10010916769	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	I
										Recovering/Resolving - ), Headache (n/a -			
										Recovering/Resolving - ), Malaise (n/a - Not			
										Recovered/Not Resolved - ), Myalgia (n/a -			
										Recovering/Resolving - ), Nausea (1d -			
										Recovered/Resolved - ), Photophobia (n/a -			
										Recovering/Resolving - ), Pyrexia (n/a -			
EU-EC- 10010917236	10/12/2021	Spontaneous	Non Hea <b>l</b> thcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovering/Resolving - ) Hyperhidrosis (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	1
EU-EC- 10010917240	10/12/2021	Spontaneous	Professional	Area European Economic	Not available	12-17 Years	Not Specified	Female	No	- )  Dysmenorrhoea (n/a - Not Recovered/Not	- n/a - Intramuscular])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	10
10010917240				Area	avaliable	rears	Specified			Resolved - ), Heavy menstrual bleeding (n/a -	- n/a - Intramuscular])		
EU-EC- 10010917348	10/12/2021	Spontaneous	Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown - ) Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>I</u> 0
EU-EC- 10010917528	10/12/2021	Spontaneous	Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eczema (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>I</u> 0
EU-EC- 10010917532	10/12/2021	Spontaneous	Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	10
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010917702	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a3mL - Intramuscular])	Not reported	<u>I0</u>
										Vomiting (n/a - Recovered/Resolved - )			
EU-EC- 10010918190	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	10
										Hyporeflexia (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Muscular weakness (n/a - Not Recovered/Not Resolved - ),			
										Neurological symptom (n/a - Not Recovered/Not Resolved - ),			
		 pa.eu/anal								Paraparesis (n/a -			6

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										Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sensory disturbance (n/a - Not Recovered/Not Resolved - ),			
										Urinary incontinence (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010918195	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved - ), Myocarditis (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
	10/10/10001			_						Medically Important Condition)			
EU-EC- 10010918370	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	маје	No	Dysphagia (48h - Recovered/Resolved - ), Oesophageal pain	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										(48h - Recovered/Resolved - )			
EU-EC- 10010918884	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Unknown - ), Vaccination site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										(n/a - Unknown - ),  Vaccination site swelling (n/a -			
EU-EC- 10010918959	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown - ) Blindness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Eyelid irritation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Retinal detachment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Vitreous haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10010919059	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	i	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010919191	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Unknown - ), Menstrual disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010919195	10/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	(n/a - Unknown - ) Rash (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10010919417	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	- n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-	10/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Herpes zoster (21d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10010919599			Healthcare Professional		available	Years				- ), Rash (21d -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010919731	10/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Fatigue (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
			Professional	Area						- ), Malaise (1d - Recovering/Resolving	- n/a - n/a])		
										Nausea (1d - Recovering/Resolving			
										- ), Pyrexia (1d - Recovering/Resolving			
										Vaccination site pain			
										Recovering/Resolving -), Vomiting (1d -			
EU-EC- 10010920173	10/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving - ) Type 1 diabetes mellitus (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
10010320173			Professional		avaijabje	rears				Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling)	- 2{DF} - n/a])		
EU-EC- 10010920188	10/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),			
										Menstrual disorder (n/a - Not Recovered/Not Resolved - ),			
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010920385	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Hospitalisation), Eosinophilic oesophagitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Oesophageal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10010920386	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Hospitalisation)  Pain in extremity (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010921243	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	New daily persistent headache (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Peripheral swelling (3d - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site erythema (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010921779	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010922295	10/12/2021	Spontaneous	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 - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010922403	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR

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										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])		
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010922497		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	·	ICSR
EU-EC- 10010922518	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010922522	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (2d - Recovered/Resolved - ), Intermenstrual bleeding (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010922571	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (52d - Recovered/Resolved - ), Hypersomnia (52d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Pruritus (n/a - Not Recovered/Not Resolved - ), Somnolence (52d - Recovered/Resolved - )			
EU-EC- 10010922612	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Asthenia (n/a - Not Recovered/Not Resolved - ), Decreased appetite (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
511.50	40/42/2024	6	N		N	12.17	A 1.1			Recovered/Not Resolved - )	COMPNATA STOTINAMED AND	N. b b. d	TOOD
EU-EC- 10010922629		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Urticaria (n/a - Recovering/Resolving - )	Drug withdrawn - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10010922633	10/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Burning sensation (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010922675	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Rash pustular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010922698	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Recovering/Resolving - )		Not reported	ICSR
EU-EC- 10010922723	10/12/2021	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	<u>ICSR</u>
EU-EC- 10010922954	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LYMECYCLINE] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
										Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010922998	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes simplex (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010923015	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010923025	10/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>

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				Area						Unknown - )	Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10010923030	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
										Palpitations (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010923039	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (15min - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010923090	10/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL -	Not reported	ICS
										- ), Influenza like illness (2wk - Recovered/Resolved - ), Urticaria (2wk -	Intramuscular])		
EU-EC-	10/12/2021	Cnontangous	U o a lith a a v o	Furancan	Not	12.17	Adalasaant	Malo	No	Recovered/Resolved	COMPONATY FTOZINAMEDANI	Not reported	ICC
10010923131	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	маю	INO	Herpes zoster (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	·	ICS
EU-EC- 10010923144	10/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICS
EU-EC- 10010923233	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
										Rash (n/a - Not Recovered/Not Resolved - ),	and an escalar jy		
										Vaccination site pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010923249	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Not Recovered/Not Resolved - ),	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	[ESCITALOPRAM] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Vaccination site oedema (n/a - Not Recovered/Not	Intramuscular])		
EU-EC- 10010923256	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - ) Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
										Nausea (n/a - Not Recovered/Not Resolved - ),	Intramuscular])		
										Tremor (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010923259	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010923303	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (10d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL, PLACEBO] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 10010923603	10/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010923609	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acute disseminated encephalomyelitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[DERMATOPHAGOIDES FARINAE EXTRACT, DERMATOPHAGOIDES PTERONYSSINUS EXTRACT] (C - Mite allergy - n/a - [n/a - n/a - Oral])	ICS
										CSF cell count increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Demyelination (n/a - Unknown - Other Medically Important Condition),			
										Encephalopathy (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a -			

## Run Line Listing Report

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											Hospitalisation),				
											Magnetic resonance imaging abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),				
											Meningitis bacterial (n/a - Unknown - Other Medically Important Condition),				
											Nervous system disorder (n/a - Unknown - ),				
											Nuchal rigidity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),				
											Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),				
											Somnolence (n/a - Unknown - ),				
											White matter lesion (n/a - Unknown - )				
	EU-EC- 10010923621	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Encephalitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	,
											Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),				
											Meningoencephalitis bacterial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),				
											Meningoencephalitis viral (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),				
											Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically				



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