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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10009070303	18/06/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (48h - Recovered/Resolved -), Nausea (48h - Recovered/Resolved -), Pain (48h -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Pyrexia (48h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009070419	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
										Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)		[THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009071106	18/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Inappropriate affect (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009045631	17/06/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	A Fatigue (1d - Recovered/Resolved -), Nasopharyngitis (1d - Recovered/Resolved -), Oropharyngeal pain (1d - Recovered/Resolved -), Pain in extremity (1d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10009046597	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009046614	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC-	17/06/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Vomiting (n/a - Unknown - Other Medically Important Condition) Feeling abnormal	TOZINAMERAN	[BECLOMETASONE	ICSF
10009047728	3., 30, 2021		Healthcare Professional	European	available	Years	Specified			(n/a - Not Recovered/Not Resolved -), Hyperpyrexia (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [EPINEPHRINE,	
		 								Not Recovered/Not Resolved - Other	- -	EPINEPHRINE, SODIUM METABISULFITE, SODIUM	1/

U-EC- 0009047890	17/06/2021									Medically Important Condition),		CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
	17/06/2021									1			
	17/06/2021									Pain (n/a - Not Recovered/Not			
	17,00,2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Resolved -) Appetite disorder	COMIRNATY	Not reported	ICS
		Spontaneous	Healthcare Professional	Economic	available	Years	Specified	riale		(n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>IC.</u>
										Chills (n/a - Not Recovered/Not Resolved -),	n/a - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved -)			
J-EC- 0009049080	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	IC
										Infection (n/a - Unknown - Caused/Prolonged	applicable - [n/a - n/a - n/a])		
										Hospitalisation), Loss of consciousness (n/a -			
										Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Tremor (n/a - Unknown -			
										Caused/Prolonged Hospitalisation)			
-EC- 009050317	17/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Other Medically Important	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	10
										Condition), Swelling face (0d - Recovering/Resolving - Other Medically Important Condition),	MODIFIED) [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular])		
										Swelling of eyelid (0d			
										Recovering/Resolving - Other Medically Important Condition)			
J-EC- 1 009051415	17/06/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Psychotic disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	[BACLOFEN] (C - n/a - n/a - [n/a - n/a - n/a]), [CHLORPROTHIXENE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	10
										поѕрісанзаціон)	Intramuscular])	[RISPERIDONE] (C - n/a -	
J-EC- 1 0009052374	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	n/a - [n/a - n/a - n/a]) LANTUS [INSULIN GLARGINE] (C - Type 1 diabetes mellitus - n/a -	10
				Area						Bone pain (n/a - Unknown -),	immunisation - Not applicable - [1d - n/a - n/a])	[n/a - n/a - n/a]), [INSULIN ASPART] (C - Type 1 diabetes mellitus -	
										Chest pain (n/a - Recovered/Resolved -),		n/a - [n/a - n/a - n/a]), [LORATADINE] (C - Seasonal allergy - n/a -	
										Chills (n/a - Unknown -), Dehydration (n/a -		[n/a - n/a - Oral])	
										Unknown -), Diarrhoea (n/a -			
										Unknown -), Fatigue (n/a - Unknown -),			
										Headache (n/a - Unknown -),			
										Heart rate increased (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -),			

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										Unknown -),			
										Nausea (n/a - Unknown -),			
										Pallor (n/a - Unknown -),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
										Sleep disorder (n/a - Unknown -),			
										Vomiting (n/a - Unknown -)			
EU-EC- 10009052472	17/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009055865	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Lip injury (n/a - Recovering/Resolving - Other Medically Important Condition), Seizure (n/a -			
										Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009029807	16/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pain in extremity (n/a - Recovering/Resolving -)			
EU-EC- 10009031619	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haematoma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009031839	16/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (2d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug -	[MESALAZINE] (C - Colitis ulcerative - n/a - [n/a - 1{DF} - Oral])	ICSR
										Dyspnoea (2d - Recovered/Resolved - Other Medically Important Condition),	Intramuscular])		
										Headache (2d - Recovered/Resolved - Other Medically Important Condition),			
										Injection site pain (2d - Recovered/Resolved - Other Medically Important Condition),			
										Lymphadenopathy (2d - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral swelling (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009031991	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ecchymosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSR
										Epistaxis (n/a - Not Recovered/Not Resolved -	Intramuscular])		

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										Caused/Prolonged Hospitalisation), Haemorrhage (n/a -			
										Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Platelet count decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10009032363	16/06/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										ĺ	immunisation - n/a - [n/a3mL - Intramuscular])		
EU-EC- 10009032944	16/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[BIFIDOBACTERIUM LACTIS] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Dyskinesia (n/a - Recovering/Resolving -),	applicable - [n/a - n/a - n/a])	[FISH OIL] (C - n/a - n/a - [n/a - n/a - n/a - n/a]), [MAGNESIUM CITRATE] (C	
										Heart rate increased (n/a - Recovering/Resolving		n/a - n/a - [n/a - n/a - n/a]), [THIAMINE, PYRIDOXINE	
										Nausea (n/a - Recovering/Resolving		HYDROCHLORIDE, VITAMIN B] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Pallor (n/a - Recovering/Resolving -),		[VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tremor (n/a - Recovering/Resolving -),			
										Vision blurred (n/a - Recovering/Resolving -)			
EU-EC- 10009034306	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Brain natriuretic peptide increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009035487	16/06/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Acute coronary syndrome (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Cough (n/a - Unknown - Other Medically Important Condition),	,,, u ₁ ,		
										Dysphagia (n/a - Unknown - Other Medically Important			

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										Condition), Headache (n/a - Unknown - Other			
										Medically Important Condition), Myalgia (n/a -			
										Unknown - Other Medically Important Condition),			
										Myopericarditis (n/a - Unknown - Other Medically Important Condition),			
										Odynophagia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009037143	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[FEXOFENADINE HYDROCHLORIDE] (C - Hypersensitivity, Rhinitis allergic - n/a - [n/a - n/a - Oral])	ICSR
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	, v		
										Tachycardia (n/a - Unknown - Other Medically Important Condition),			
										Throat tightness (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10009039274	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Anaphylactic shock (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicate]	Not reported	ICSR
EU-EC- 10009040007	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Generalised tonic- clonic seizure (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL -	Not reported	ICSR
EU-EC- 10009017976	15/06/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -), Tonsillitis (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009018020	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009018471	15/06/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a	Not reported	ICSR
										Dizziness (n/a - Recovered/Resolved -), Headache (n/a -	- [n/a - n/a - Intramuscular])		
										Recovered/Resolved			
EU-EC- 10009019611	15/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pharyngeal swelling (n/a - Recovered/Resolved - Other Medically Important Condition)	11/a - 11/a] <i>)</i>		
EU-EC- 10009019867	15/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Burning sensation (n/a - Recovered/Resolved -), Disorientation (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Dizziness (n/a -			
										Recovered/Resolved -), Ear discomfort (n/a -			
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										Recovered/Resolved -),			
										Flatulence (n/a - Recovered/Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Heart rate decreased (n/a - Recovered/Resolved -),			
										Hyperhidrosis (n/a - Recovered/Resolved -),			
										Muscle tightness (n/a			
										Recovered/Resolved -),			
										Oropharyngeal discomfort (n/a - Recovered/Resolved -),			
										Pallor (n/a - Unknown -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009025234	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
EU-EC- 10009027682	15/06/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -),	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Area			·			Cough (n/a - Unknown -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Fatigue (n/a - Unknown -),	.,,,,,,		
										Feeling cold (n/a - Unknown -),			
										Feeling hot (n/a - Unknown -),			
										Headache (n/a - Recovering/Resolving -),			
										Pyrexia (1d - Recovered/Resolved			
EU-EC- 10009028947	15/06/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Swelling face (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	11/a - 11/a])		
EU-EC- 10009029184	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Balance disorder (3d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE, PROCHLORPERAZINE MALEATE BP] (C - Dizziness - n/a - [n/a - n/a - n/a])	ICSR
										Dizziness (3d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009014563	14/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[CEFALEXIN] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Headache (15h - Recovered/Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PHENPROCOUMON] (C - n/a - n/a - [n/a - n/a - n/a])	
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10008996198		Spontaneous		European Economic	Not available		Not Specified	Female	No	Injection site swelling (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

			Professional							Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009002235	12/06/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 1.0008988446	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Fall (n/a - Unknown -), Gait disturbance (n/a - Not Recovered/Not Resolved -), Head injury (n/a - Unknown -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Unknown -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10008989238	11/06/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving -), Paraesthesia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 1.0008965856	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 1.0008966089	10/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Recovering/Resolving - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 1.0008966649	10/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aggression (n/a - Not Recovered/Not Resolved -), Condition aggravated (n/a - Not Recovered/Not Resolved -), Coprolalia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Not Recovered/Not Resolved -), Head discomfort (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	DULOXETINE [DULOXETINE, DULOXETINE, HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATOMOXETINE, ATOMOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORATADINE] (C - n/a - n/a - n/a - [n/a - n/a - n/a])	

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										Seizure like phenomena (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Somnolence (n/a - Not Recovered/Not Resolved -),			
										Tic (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10008967185	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Puncture site hypoaesthesia (n/a - Not Recovered/Not Resolved -), Puncture site pain	applicable - [n/a - 1{DF} -	[ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE, LACTOSE ANHYDROUS, LACTOSE MONOHYDRATE] (C - Hormonal contraception -	ICSR
										(n/a - Not Recovered/Not Resolved -)	Intramuscular])	Dose not changed - [n/a - n/a - Oral])	
EU-EC- 10008967420	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU EC	10/06/2021	Casabanasia	Non	F	Nat	12.17	Net	Mala	Ne	Fatigue (n/a - Not Recovered/Not Resolved -)	COMIDNIATY	Not worsels	TCCD
EU-EC- 10008968808	10/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovered/Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA	Not reported	ICSR
										Nausea (n/a - Recovered/Resolved -), Pruritus (4d -	VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19		
										Recovered/Resolved -), Pruritus (n/a - Recovering/Resolving	immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10008971535	10/06/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	-) Asthenia (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN]	[TIMOLOL, TIMOLOL MALEATE] (C - Eye injury -	ICSR
			Professional	Economic Area						Resolved -), Blood pressure fluctuation (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	n/a - [n/a - n/a - n/a])	
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Disturbance in attention (n/a - Unknown -),			
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Heart rate abnormal (n/a - Not Recovered/Not Resolved -),			
										Loss of personal independence in daily activities (n/a - Unknown -),			
										Muscle atrophy (n/a - Unknown - Other Medically Important Condition),			
										Somnolence (n/a - Unknown -),			
										Weight decreased (n/a - Unknown - Other Medically Important Condition)			

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EU-EC- 10008973754	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Unknown -), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Injection site pain (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (5d - Unknown -), Tachycardia (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown -), Vomiting (n/a -			
EU-EC- 10008974736	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Arthralgia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[LEVOCABASTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Injection site swelling (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a])	[LEVOCABASTINE, LEVOCABASTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10008979043	10/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	Intramuscular])		
EU-EC- 10008953895	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Unknown -),			
EU-EC- 10008956188	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Unknown -) Headache (12h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
										Malaise (12h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Muscular weakness (8h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Sensory level abnormal (12h - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10008960307	09/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Blood creatine phosphokinase increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
https://dap.ei	ma aurana	 	ce/eaw dii3) PGo						Chest pain (n/a -			9/56

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										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myocardial injury (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Troponin increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10008961642		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008961872		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	used for unknown indication - n/a - [n/a - n/a	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved -), Kidney infection (n/a	applicable - [n/a - n/a - n/a])		
										Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Urinary tract infection (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008962541		Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [1d - n/a - n/a])		
										Pain in extremity (3d - Recovered/Resolved -),			
										Sluggishness (n/a - Recovering/Resolving -)			
EU-EC- 10008963210		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Glossodynia (n/a - Not Recovered/Not Resolved - Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[FLUTICASONE PROPIONATE] (C - Hypersensitivity - n/a - [n/a - 200ug - n/a]),	<u>ICSR</u>
										Odynophagia (n/a - Not Recovered/Not Resolved - Other	applicable - [n/a - n/a - n/a])	[LORATADINE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a])	

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										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Disabling),			
										Speech disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tongue movement disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008963839	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	<u>ICSR</u>
EU-EC- 10008934341	08/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10008938724	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	, ,		
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a -			
										Unknown - Caused/Prolonged Hospitalisation),			
										(n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10008938768	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10008938778	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008939303	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10008940002	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10008940308	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008941919	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (1d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Choking sensation (n/a - Unknown -),	applicable - [n/a - n/a - n/a])		
										Dysphagia (n/a - Unknown -),			
										Hypertension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008943427	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10008943493	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (0d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)		Not reported	ICS
EU-EC- 10008944263	08/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Post viral fatigue syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC- 10008948255	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - n/a])	Not reported	ICS
										Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation),	.Sine ilyaj)		
										Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pharyngeal swelling (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pruritus (n/a - Unknown -			

										ng report			
										Caused/Prolonged Hospitalisation),			
										Spinal pain (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Swelling face (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Swollen tongue (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10008949928		Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Headache (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Recovering/Resolving -)			
EU-EC- 10008922570		Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
				7.1.00						Heart rate increased (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Hyperventilation (n/a			
										Recovering/Resolving - Other Medically Important Condition),			
										Muscle spasms (n/a - Unknown -),			
										Respiratory rate increased (n/a - Recovering/Resolving -),			
										Tremor (n/a - Unknown -)			
EU-EC- 10008922657	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	applicable - [1d - n/a - n/a])		
EU-EC- 10008923484		Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	HYDROCHLORIDE] (C -	<u>ICSR</u>
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])	Anxiety - n/a - [n/a - n/a - n/a]), [CLINDAMYCIN, CLINDAMYCIN HYDROCHLORIDE,	
										Nasal dryness (n/a - Recovering/Resolving - Other Medically Important		CLINDAMYCIN PHOSPHATE] (C - Acne - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE	
										Condition), Restless legs syndrome (n/a - Not		HYDROCHLORIDE] (C - Anxiety - n/a - [110d - n/a - n/a])	
										Recovered/Not Resolved - Other Medically Important Condition)			

EU-EC- 10008929036	07/06/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Colitis ulcerative (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AZATHIOPRINE] (C - Colitis ulcerative - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
EU-EC- 10008929788	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paresis (24h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008934887	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaphylactic reaction (4h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Depressed level of consciousness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Feeling hot (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hypotension (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	05/06/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Vision blurred (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation) Arthralqia (n/a -	COMIRNATY	Not reported	ICSR
10008914048			Healthcare	Economic Area	available	Years	Specified			Recovering/Resolving -), Chills (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Injection site inflammation (n/a - Recovering/Resolving -),			
										Injection site pain (n/a - Recovering/Resolving -),			
										Injection site warmth (n/a - Recovering/Resolving -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (0d -			
EU-EC- 10008914096	05/06/2021	Spontaneous	Healthcare	Economic	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Chills (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
			Professional	Aled						-), Fatigue (n/a - Recovering/Resolving -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Headache (n/a - Recovering/Resolving -),			
										Malaise (2d - Recovered/Resolved -), Myalgia (1d -			
EU-EC- 10008895639	04/06/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) COVID-19 (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR
				Economic Area			,			Medically Important Condition), Drug ineffective (n/a - Unknown - Other	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		

										Medically Important Condition)			
EU-EC- .0008896364	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Postural orthostatic tachycardia syndrome (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
:U-EC- 0008899521	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved - Disabling) Haematoma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - p/a - p/a])	Not reported	ICSF
EU-EC- 1.0008902760	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No No	Arthralgia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Central nervous system vasculitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea haemorrhagic (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Eosinophilia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Eosinophilic colitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gastrointestinal motility disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	HYDROXYCARBAMIDE [HYDROXYCARBAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CO-TRIMOXAZOLE, SULFAMETHOXAZOLE, TRIMETHOPRIM, TRIMETHOPRIM, TRIMETHOPRIM, BP, SULFAMETHOXAZOLE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [CYCLOPHOSPHAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [IVERMECTIN] (C - n/a - n/a - n/a - [n/a - n/a - n/a]), [METHYLPREDNISOLONE, SODIUM SUCCINATE] (C - n/a - n/a)], [OMEPRAZOLE] (C - n/a - n/a)], [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - n/a - [n/a - n/a - n/a])	

										Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Leukocytosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nervous system disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Photophobia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Venous thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Venous thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) Cher Medically Important Condition)			
EU-EC- 10008909593	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (2d - Recovered/Resolved - Other Medically Important Condition), Diyspnoea (n/a - Not Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heart rate increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rhinorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition))	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOTRIMAZOLE] (C - n/a - n/a - [n/a - n/a - Topical])	ICSR
EU-EC- 10008912152	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Anaphylactic shock (n/a - Unknown - Life Threatening), Cardiovascular disorder (n/a - Unknown - Life Threatening), Crying (n/a - Unknown - Life Threatening), Erythema (n/a - Unknown - Life	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10008912207	04/06/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Threatening), Heart rate increased (n/a - Recovering/Resolving - Life Threatening), Pain in extremity (n/a - Unknown -), Rash (n/a - Recovering/Resolving - Life Threatening), Swelling (n/a - Unknown - Life Threatening) Syncope (n/a - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN]	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
			Professional	Economic Area						- Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10008912284	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN] (TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008877491	03/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Chills (n/a - Recovering/Resolving -), Escherichia urinary tract infection (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Thrombocytopenia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008887075	03/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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>
EU-EC- 10008863048	02/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10008863533	02/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10008864333	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved -), Dizziness (n/a - Recovering/Resolving -), Feeling abnormal (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - 40ug - n/a]), [CALCIUM FLUORATUM D15, CALCIUM D15, CALCIUM D15, CALCIUM D16, CALCIUM CARBONICUM HAHNEMANNI D10, MATRICARIA RECUTITA D10, SULFUR D12,	ICSR

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										Resolved -), Headache (n/a - Not Recovered/Not Resolved -),		MERCURIUS SOLUBILIS HAHNEMANNI D15] (C - Hypersensitivity - n/a - [n/a - 4[drp] - n/a]),	
										Hypoaesthesia (1d - Recovered/Resolved -),		[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 20mg - Oral]),	
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically		[ISOTRETINOIN] (C - Acne - n/a - [n/a - 80mg - Oral]),	
										Important Condition), Malaise (n/a -		[MOMETASONE FUROATE] (C - Hypersensitivity - n/a - [n/a - 100ug - n/a]), [PARACETAMOL] (C - Pain -	
										Unknown -), Nausea (n/a - Not Recovered/Not Resolved -),		n/a - [n/a - 1000mg - Oral]), [SODIUM CHLORIDE] (C -	
										Pain in extremity (n/a - Unknown -),		Hypersensitivity - n/a - [n/a - n/a - Nasal])	
										Paraesthesia (1d - Recovered/Resolved -),			
										Rash (n/a - Not Recovered/Not Resolved -), Vaccination site pain			
										(n/a - Recovering/Resolving -),			
EU-EC- 10008864457	02/06/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Vascular injury (n/a - Unknown -) Chest pain (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR
				Economic Area						Cough (3d - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Fatigue (3d - Recovered/Resolved -),			
										Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10008865080	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008865134	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008865146	02/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Recovering/Resolving -), Pain in extremity (n/a -	n/a - n/a])		
										Recovering/Resolving -), Syncope (n/a -			
EU-EC-	02/06/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovering/Resolving - Other Medically Important Condition) Coagulopathy (n/a -	TOZINAMERAN	Not reported	ICSR

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United State Continues C	10008866940			Professional	Economic	available	Years	Specified			Hepatic function abnormal (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a -		
BLFC 02/6/222 Sextlanous Non-														
Bi-14C											Renal impairment (n/a - Unknown - Other Medically Important			
Part											Swelling (n/a -			
EU-EC- 1000/886/03-40 CQ2/66/2021 Spontaneous Rom Indial harm European Professoral Recovered Re											inflammatory response syndrome (n/a - Unknown - Caused/Prolonged			
EU-EC-											Troponin increased			
EU-CC 02,06/2021 Spontaneous Not Common														
EL-ECT 100/88/63-10														
No.	EU-EC- 10008868340	02/06/2021	Spontaneous	Healthcare	European Economic				Female	No	Asthenia (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
ELPCC 02/06/2021 Spontaneous Nem Not Nem Professional Economic Professional Economic Nem Profess											Unknown - Other Medically Important	n/a -		
FELF-C: O2/06/2021 Spontaneous Non Non Healthcare Professional European E											Unknown - Other Medically Important			
EU-EC- 10008869170 OZ/05/2021 Spontaneous Non Healthcare European Professional Economic Area Non Healthcare European Professional Economic Area Not Dillis (1d - Recovered/Resolved -), Dizarneas (1/4 - Recovered/Resolved -), Estigue (1d - Recovered/Resolved -), Estigue (1d - Recovered/Resolved -), Lubb discomfort (n/a - Recovered/Resolved -), Lubb discomfort (n/a - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Syrope (1/6 - Recovered/Resolved -), S											Malaise (n/a - Unknown - Other Medically Important			
EU-EC- 10008869170 20/2/05/2021 Spontaneous Non Healthcare Professional Recovered/Resolved Not Not Not Recovered/Resolved Not Not Recovered/Resolved Not Not Not Recovered/Resolved Not Not Not Recovered/Resolved Not Not														
Healthcare Economic Professional P											Unknown - Other Medically Important			
Diarrhoea (1d - Recovered/Resolved), Dizziness (n/a - Recovered/Resolved), Fatigue (1d - Recovered/Resolved), Hypokinesia (n/a - Recovered/Resolved), Lethargy (n/a - Recovered/Resolved), Lethargy (n/a - Recovered/Resolved), Limb discomfort (n/a - Recovered/Resolved), Nausea (1d - Recovered/Resolved), Pain (1d - Recovered/Resolved), Pain (1d - Recovered/Resolved), Pyrexia (1d - Recovered/Resolved),	EU-EC- 10008869170	02/06/2021	Spontaneous	Healthcare	European Economic				Female	No	Chills (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19	DIHYDROCHLORIDE] (C - Seasonal allergy - n/a -	ICSF
Dizziness (n/a - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Hypokinesia (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Limb discomfort (n/a - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)					Area						Recovered/Resolved	applicable - [n/a - n/a -	[MOMETASONE FUROATE] (C - Seasonal allergy - n/a -	
Recovered/Resolved -), Hypokinesia (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Limb discomfort (n/a - Recovered/Resolved -), Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important											Recovered/Resolved			
Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Limb discomfort (n/a - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -) (The Medically Important											Recovered/Resolved			
Recovered/Resolved -), Limb discomfort (n/a - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important											Recovered/Resolved			
- Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important											Recovered/Resolved			
-), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important											Limb discomfort (n/a			
Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important														
Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important											Recovered/Resolved			
Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important											Recovered/Resolved			
Syncope (n/a - Recovered/Resolved - Other Medically Important											Recovered/Resolved			
											Syncope (n/a - Recovered/Resolved - Other Medically			

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										Tinnitus (n/a - Recovered/Resolved			
EU-EC- 10008869373	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Lip swelling (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Pruritus (n/a - Unknown -),			
										Rash (n/a - Unknown - Other Medically Important Condition),			
										Rash macular (n/a - Unknown -),			
										Swelling face (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008869413	02/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10008870922	02/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angiopathy (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Autoimmune disorder (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008873299	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Accidental exposure to product (n/a - Unknown -), Needle issue (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Unknown -), Underdose (n/a - Unknown -),	n/a - n/a])		
										Vaccination site haemorrhage (n/a - Unknown -)			
EU-EC- 10008873976	02/06/2021	Spontaneous	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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008875880	02/06/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]),	ICSR
										Arthralgia (n/a - Unknown - Other Medically Important	n/a - Intramuscular])	[EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - n/a -	
										Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition),		n/a - [n/a - 40mg - Oral]), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - Urticaria - n/a - [n/a -	
										Hypersensitivity (n/a - Unknown - Other Medically Important Condition),		75mg - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - 10mg	
										Pyrexia (n/a - Unknown - Other Medically Important Condition),		- Oral])	
										Serum sickness (n/a - Unknown - Other Medically Important			
										Condition)			

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			Professional	Area						Resolved -), Fatigue (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	n/a - [n/a - n/a - n/a])	
EU-EC- 10008847772	01/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Vertigo (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not			
EU 50	0.1 (0.5 (0.0.)			_		10.15				Resolved -)	001470114707		
EU-EC- 10008849425	01/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Flushing (7d - Recovered/Resolved -), Swelling (7d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10008852060	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	[ISOTRETINOIN] (C - Acne - n/a - [79d - n/a - Oral])	ICSR
EU-EC- 10008852404	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Incorrect dose administered (n/a - Unknown -), Product leakage (n/a - Unknown -),	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NORETHISTERONE ACETATE, ETHINYLESTRADIOL, FERROUS FUMARATE] (C - Contraception - n/a - [n/a - n/a - Oral])	ICSR
										Sneezing (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site erythema (3d - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	01/06/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Vaccination site swelling (n/a - Unknown - Other Medically Important Condition) Abdominal pain (n/a	COMIRNATY	METHOTREXATE	ICSR
10008853125	01/00/2021	Spontaneous	Professional	Economic Area	available	Years	Specified	remale		- Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[METHOTREXATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a -	mamascalary	[VITAMIN D] (C - n/a - n/a - [n/a - 100[iU] - n/a])	
										Recovering/Resolving - Caused/Prolonged Hospitalisation), Product administered			
										to patient of inappropriate age (n/a - Unknown -), Vomiting (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10008855676	01/06/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -),			
		I .	1	1	1	1	1	1	1	1 1 3 1 3 1 3 1 4 1 5 1 4 1 5 1 5 1 5 1 5 1 5 1 5 1 5	I .	i .	1

										Recovered/Not Resolved -)			
EU-EC- 10008856137	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Discomfort (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Feeling hot (n/a - Unknown -), Headache (n/a - Unknown -), Rash erythematous (n/a - Unknown -), Thrombosis (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10008857438	01/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Diarrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10008859927	01/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008860327	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008836746	31/05/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	[DESOGESTREL, ETHINYLESTRADIOL] (C - Ill-defined disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10008837782	31/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Lethargy (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Neck pain (n/a - Unknown -), Pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -), Pyrexia (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008837787	31/05/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [LYMECYCLINE] (C - Acne - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a	
EU-EC-	31/05/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Seizure (n/a -	TOZINAMERAN	- n/a]) Not reported	ICSR

10008843569	5.00		Professional	European Economic Area	available	Years	Specified		e Listi	Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10008847479	31/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -), Dysphonia (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
										Extremity contracture (n/a - Recovering/Resolving -),			
										Fall (n/a - Recovering/Resolving -),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Recovering/Resolving -),			
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10008849003	31/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Left ventricular dysfunction (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008835544	30/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Autism spectrum disorder (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Cerebral palsy (n/a - Unknown - Other Medically Important Condition)	, , ,		
EU-EC- 10008824750	29/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICS
										Myalgia (n/a - Recovered/Resolved			
EU-EC- 10008824905	29/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10008825155	29/05/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug -	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),	Intramuscular])	[AMYLASE, LIPASE, PROTEASE, PANCREALIPASE, PANCREAS POWDER, PANCREAS POWDER FROM PORCINE, PANCREATIN,	
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)		PANCREATIN, PANCREATIN BP] (C - Blood cholesterol - n/a - [n/a - 150mg - n/a])	
EU-EC- 10008825649	29/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza (n/a - Recovered/Resolved -), Injection site pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug -	Not reported	ICS
EU-EC-	29/05/2021	Spontaneous		European	Not	12-17	Not Specified	Female	No	Recovered/Resolved -) Headache (n/a - Not	Intramuscular]) COMIRNATY	[METHYLPHENIDATE	ICS
10008825901			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	

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										Malaise (n/a - Recovering/Resolving -),	applicable - [n/a - n/a - n/a])		
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10008813700	28/05/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (7d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Delirium (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Dysarthria (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (7d - Recovered/Resolved - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition),			
										Myalgia (5d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving -),			
										Off label use (n/a - Unknown - Other Medically Important Condition),			
										Overdose (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovering/Resolving -),			
										Rash (5d - Recovered/Resolved - Other Medically Important Condition),			
										Swelling face (n/a - Recovering/Resolving -)			
EU-EC- 10008817261	28/05/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008817304	28/05/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Condition) Lymphadenopathy (n/a -	TOZINAMERAN [TOZINAMERAN]	[BECLOMETASONE] (C - n/a - n/a - [n/a - n/a -	ICSR
1000001/304			Professional		avaliable	Icais	эрссиеч			Recovering/Resolving - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	n/a])	
										Rash erythematous (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rash pruritic (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10008817709	28/05/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Cyanosis (1d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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				Economic Area						Important Condition), Hyperhidrosis (1d - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Peripheral circulatory failure (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008817810	28/05/2021	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 Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Mydriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	· · · ·		
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008820941	28/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008821180	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovering/Resolving -), Headache (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										-), Influenza like illness (1d - Recovering/Resolving -),			
										Limb discomfort (1d - Recovering/Resolving -),			
										Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10008824417	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10008824513	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008783324	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Ligament rupture (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	26/05/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Pain in extremity (n/a - Unknown -) Myocarditis (n/a -	TOZINAMERAN	Not reported	ICSR
10008786478			Professional	European Economic Area	available	Years	Specified			Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10008788011	26/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10008790294	26/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy (n/a - Recovering/Resolving			

									. LIST				
										- Other Medically Important Condition)			
EU-EC- 10008794644	26/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (2d - Recovering/Resolving -), Chills (2d - Recovering/Resolving -), Injection site pain (2d - Recovering/Resolving -), Vaccination site pain (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovering/Resolving			
EU-EC- 10008767139	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUTYLSCOPOLAMINE, HYOSCINE BUTYLBROMIDE] (C - Irritable bowel syndrome - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE, SALMETEROL, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - n/a]),	ICSR
												[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a	
EU-EC- 10008768779	25/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - Intramuscular])	- n/a]) Not reported	ICSR
										Somnolence (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10008769739	25/05/2021	Spontaneous	Non 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 - [n/a - n/a - n/a])	[NORETHISTERONE ACETATE, ETHINYLESTRADIOL] (C - Menstrual disorder - n/a - [n/a - n/a - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a -	ICSR
EU-EC- 10008771889	25/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Oral]) Not reported	ICSR
EU-EC- 10008772533	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Blood ketone body (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INSULIN DEGLUDEC [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Unknown - Other			
EU-EC- 10008773382	25/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Medically Important Condition) Chills (1d - Recovered/Resolved - Disabling), Fatigue (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

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Process Proc											- Disabling),			
Discrepance Property Proper											Recovered/Resolved			
December											Recovered/Resolved			
EU-EC 24/95/2021 Spellareous Non New Professor Specified Specifi											Recovered/Resolved			
Machine Mach											Recovered/Resolved			
Purple P		24/05/2021	Spontaneous	Healthcare	Economic				Male	No	Recovered/Not	[TOZINAMERAN]	Not reported	<u>ICSR</u>
EU-SC 24/05/2021 Sportaneous Not European Not 12-17 Not				Troressional	Arcu						Chills (n/a - Not Recovered/Not	immunisation - Not applicable - [n/a -		
EI-EC- 24/05/2021 Spontaneous Non Halliflicare European Not Halliflicare European Non Halliflicare Eur											Headache (n/a - Not Recovered/Not			
RILFEC 24,05/2021 Spontaneous Non Healthcare Non Specified Non Spe											Recovered/Not			
EU-EC- 10000730373 21/05/2021 Spontaneous Nor Surrogen Nor Nor Surrogen Nor											Recovered/Not			
Healthcare Economic Professional Avea Walable Wa											Recovered/Not Resolved -)			
EU-EC- 100087/3575 21/05/2021 Spontaneous Non Healthcare Professional Area Not Specified Female Not Recovered/Not		24/05/2021	Spontaneous	Healthcare	Economic				Female	No	Recovered/Not Resolved -),	[TOZINAMERAN] (S - n/a - Not applicable - [n/a -	Migraine - n/a - [n/a - n/a - n/a]),	
EU-EC- 10008726375 21/05/2021 Spontaneous Non European Not Hoalthcare Economic Professional Area Not Specified Vears Specified Female Not Specified											Recovered/Not Resolved -),	n/a - n/a]) 	HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a -	
Healthcare Professional Profes	EU-EC-	21/05/2021	Spontaneous	Non	European	Not	12-17	Not	Fomalo	No	Not Recovered/Not Resolved -)	COMIDNATY	Not reported	TCCD
EU-EC- 1008732058 21/05/2021 Spontaneous Non European Not 12-17 Not Professional Area Not Recovered/Not Recovered/		21/05/2021	Spontaneous	Healthcare	Economic				remale	INO	(n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19	Not reported	ICSK
Healthcare Economic Professional Area Area Professional Area Area Professional											Malaise (n/a - Recovering/Resolving	- [n/a - 1{DF} -		
EU-EC- 1008732058 Spontaneous Non Healthcare Professional Professional Surgeon Not Recovered		21/05/2021	Spontaneous	Healthcare	Economic				Male	No	Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC- 10008732058 21/05/2021 Spontaneous Non Healthcare Professional European Healthcare Professional Area Economic Area European Healthcare Professional Economic Area European Healthcare Professional Economic Area Euro											Recovered/Not Resolved -),			
EU-EC- 1008732058 21/05/2021 Spontaneous Non Healthcare Professional Area Profession											Recovered/Not Resolved -),			
Healthcare Professional Area Healthcare Professional Area Healthcare Professional Area EU-EC- 10008735722 EU-EC- 10008737677 EU-EC- 100087376	FILEC.	21/05/2021	Constant	Nam		Nat	12.17	Net	F	No	Recovered/Not Resolved -)	COMMUNICATIV	Not an extend	TCCD
EU-EC- 10008737677 EU-EC- 10008737678 EUropean Professional Prof		21/05/2021	Spontaneous	Healthcare	Economic				Female	NO	Recovering/Resolving	[TOZINAMERAN] (S - COVID-19	Not reported	ICSK
EU-EC- 10008735722											Recovered/Not	applicable - [n/a -		
EU-EC- 1008737677											Recovered/Not			
Professional Economic Area Professional European Professional European Professional Area Professional European Pro											Recovered/Not Resolved -)			
Healthcare Professional European Economic Area Healthcare Professional European Economic Area Feature Professional European Economic Area European Economic Area Feature Professional European Economic Area European Economic Area Feature Professional Economic Area Feature Profession Profession Area Feature Profession Profession Area Feature Profession Profession Area Feature Profession Area Feat		21/05/2021	Spontaneous		Economic				Male	No	Recovered/Resolved	(S - n/a - Unknown	Not reported	ICSR
Learning disorder (n/a - Unknown - Other Medically Important Condition), Off label use (n/a -		21/05/2021	Spontaneous	Healthcare	European Economic				Female	No	upper (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	[SOMATROPIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SOMATROPIN,	ICSR
											(n/a - Unknown - Other Medically Important	,	METACRESOL] (C - Blood growth hormone - n/a -	

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										Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008741056	21/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (12d - 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
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Heart rate abnormal (29d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Hunger (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Increased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Lethargy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Malabsorption (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Taste disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10008711292	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving -), Decreased appetite (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),			
										Hyperglycaemia (n/a - Recovering/Resolving			
						-				-)			-

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EU-EC- 10008712186	20/05/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Papule (n/a - Recovered/Resolved With Sequelae - Disabling), Scab (n/a - Recovered/Resolved With Sequelae - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008713242	20/05/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disabling) Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008714433	20/05/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aphasia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Incoherent (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown -), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Product use issue (n/a - Unknown -), Somnolence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10008716412	20/05/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Recovering/Resolving			
EU-EC-	20/05/2021	Spontaneous		Non	Not	12-17	Not	Male	No	- Other Medically Important Condition) Chest pain (n/a -	TOZINAMERAN	Not reported	ICSR
10008723663			Professional	European	available	Years	Specified			Recovered/Resolved	[TOZINAMERAN]		

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				Economic Area						- Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [n/a -		
										Troponin increased (n/a - Recovered/Resolved - Caused/Prolonged	n/a - Intramuscular])		
EU-EC- 10008697240	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Electrocardiogram abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - n/a])		
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	19/05/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation) Diarrhoea (3d -	COMIRNATY	Not reported	ICSR
10008697284	13/03/2021	Sportaneous	Professional	European Economic Area	available	Years	Specified	remaje		Recovered/Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSIX
										Generalised tonic- clonic seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	n/a - Intramuscular])		
										Hypokalaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10008705454	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Basal ganglia infarction (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	[SOTALOL, SOTALOL HYDROCHLORIDE] (C - Arrhythmia - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN	ICSR
										Facial paralysis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),	Intramuscular])	SODIUM] (Ć - n/a - n/a - [n/a - n/a - n/a])	
										Ischaemic cerebral infarction (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation),			
										Motor dysfunction (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10008707751	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Hyperhidrosis (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important	applicable - [n/a - n/a - Intramuscular])		
										Condition), Pallor (n/a - Unknown -),			
										Presyncope (n/a - Unknown -)			
EU-EC- 10008686592	18/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Streptobacillus infection (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [1d - n/a - n/a])		
EU-EC- 10008667853	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL, CAFFEINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),			
										Neck pain (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10008674310	1//05/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disease recurrence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 5mg - n/a])	ICS
										IgA nephropathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008676430	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Rash pruritic (n/a - Unknown - Other Medically Important Condition)			100
EU-EC- 10008681528	1//05/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -),	applicable - [n/a -	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICS</u>
										Pain in extremity (n/a - Recovering/Resolving -),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										White blood cell count increased (n/a - Recovering/Resolving			
EU-EC- 10008653272	15/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICS
										Headache (2d - Recovered/Resolved -),	immunisation - n/a - [n/a3mL - Intramuscular])		
										Pain (2d - Recovered/Resolved -)			
EU-EC- 10008643456	14/05/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C -	ICS
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),	1/a])	[FEROUS SULFATE] (C - Blood iron decreased - n/a - [n/a - n/a - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C -	
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),		Hypersensitivity - n/a - [n/a - n/a - n/a])	

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										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10008644014	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Confusional state (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dysarthria (n/a - Recovering/Resolving -),	applicable - [n/a - n/a - n/a])		
										Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving -),			
										Somnolence (n/a - Recovering/Resolving -),			
										Tongue discomfort (n/a - Recovering/Resolving -),			
										Vision blurred (n/a - Recovering/Resolving -)			
EU-EC- 10008631844	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -), Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug -	Not reported	ICSR
										Recovered/Resolved -), Headache (n/a -	Intramuscular])		
										Recovered/Resolved -),			
										Hyperglycaemia (n/a - Recovered/Resolved -)			
EU-EC- 10008632578	13/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Eye haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Influenza like illness (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10008632776	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphasia (30min - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Acne	ICSR
										Balance disorder (n/a - Not Recovered/Not Resolved -),	applicable - [1d -	- n/a - [n/a - n/a - n/a]), [ONDANSETRON, ONDANSETRON	
										Body temperature increased (n/a - Unknown -),		HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - Nausea -	
										Burning sensation (n/a - Unknown -),		n/a - [n/a - n/a - n/a])	
										Chest discomfort (n/a - Unknown -), Chills (n/a -			
										Unknown -), Feeling abnormal			
										(n/a - Unknown -), Insomnia (n/a -			
										Recovering/Resolving -),			

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										Tremor (n/a - Unknown -),			
										Trismus (30min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008639252	13/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Feeling hot (n/a - Unknown - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Feeling of body temperature change (n/a - Unknown - Other Medically Important Condition),			
										Flushing (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Hyperhidrosis (n/a - Unknown - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008640544	13/05/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Anaphylactic shock (0d - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition),			
										Swelling face (0d - Recovered/Resolved - Other Medically Important Condition),			
										Urticaria (0d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008604525	11/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BUSPIRONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEDROXYPROGESTERONE ACETATE] (C - n/a - n/a -	ICSR
EU-EC- 10008604559	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness unilateral (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	[n/a - n/a - n/a]) Not reported	ICSR
EU-EC- 10008611878	11/05/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (15d - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR
				Area						-), Feeding disorder	(S - COVID-19 immunisation - Drug withdrawn -		
										(15d - Recovered/Resolved	[1d - 1{DF} - Intramuscular])		
EU-EC- 10008578597	08/05/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	-) Arthralgia (3d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR
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			Professional	Economic Area						- Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d -		
										Feeling hot (1d - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Headache (3d - Recovered/Resolved - Other Medically Important Condition),			
										Myalgia (3d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008561325	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10008561453	07/05/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug -	[LAMOTRIGINE] (C - Epilepsy - n/a - [n/a - 50mg - Oral]), [RISPERIDONE] (C - Behaviour disorder - n/a -	ICSR
EU EC	07/05/222	Chauter	Haalet -	E	Net	12.17	Net	Mal-	Nic	Dimensio (: /-	Intramuscular])	[n/a - n/a - n/a])	TCCT
EU-EC- 10008563866	07/05/2021	Spontaneous		European Economic Area	Not available		Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug -	Not reported	ICSR
EU-EC-	07/05/2021	Spontaneous	Hoalthearo	Non	Not	12-17	Not	Male	No	-)	Intramuscular]) TOZINAMERAN	Not reported	TCCD
10008564342	07/05/2021	Spontaneous	Professional	Non European Economic Area	Not available	Years	Specified	Маје	INO	Dyspnoea (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Respiratory distress (n/a - Unknown - Other Medically Important Condition),	n/a - Intramuscular])		
										Sensory loss (n/a - Unknown - Other Medically Important Condition),			
										Tension (n/a - Unknown - Other Medically Important Condition),			
										Throat tightness (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008569147	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008569743	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (4d - Recovered/Resolved -), Multisystem inflammatory	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										syndrome in children (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),	Intramuscular])		
EU EO	07/05/555	Constitution	New	Nove	Note	12.1=	Note	F		Product administered to patient of inappropriate age (n/a - Unknown -)	TOTALLA		ICC
EU-EC- 10008576583	0//05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved -), Cellulitis (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		

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										Hypersensitivity (n/a - Not Recovered/Not Resolved -),			
										Overdose (n/a - Not Recovered/Not Resolved -),			
										Pemphigoid (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Peripheral swelling (n/a - Not Recovered/Not Resolved -),			
										Pruritus (n/a - Not Recovered/Not Resolved -),			
										Skin disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10008576611	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arterial thrombosis (n/a - Kecovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008556376	06/05/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	-) Seizure (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN]	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a -	ICSR
10006330370			Professional	Economic Area	available	rears	эрестеч			Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[C - Lpilejsy - I/ya -	
EU-EC- 10008556394	06/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Suspected COVID-19 (n/a - Not Recovered/Not Resolved -), Thrombosis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10008559021	06/05/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years		Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	KEPPRA [LEVETIRACETAM] (C - Seizure - n/a - [n/a - 2000mg - n/a]), [AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
EU-EC- 10008536070	05/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008523006	04/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Caused/Prolonged Hospitalisation) Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10008524780	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008524790	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Arthritis - n/a - [n/a - 15mg - n/a])	ICSR

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										Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged			
EU-EC- 10008528521	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008528529	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										C-reactive protein increased (n/a - Unknown -),			
										Musculoskeletal disorder (n/a - Unknown -),			
										Myositis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -)			
EU-EC- 10008528672	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Malaise (n/a - Unknown -),	1{DF} - n/a])		
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008528973	04/05/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])		ICSR
												MERCAPTOPURINE [MERCAPTOPURINE] (C - Colitis ulcerative - n/a - [n/a - n/a - n/a]),	
												[MESALAZINE] (C - Colitis ulcerative - n/a - [715d - n/a - n/a]),	
												[OMEPRAZOLE] (C - Gastritis - n/a - [n/a - n/a - n/a])	
EU-EC- 10008530276	04/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition aggravated (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Confusional state (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Memory impairment (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10008534522	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cerebral infarction (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INSULIN ASPART [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), INSULIN DETEMIR [INSULIN DETEMIR] (C -	ICSR

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											Important Condition),		n/a - n/a - [n/a - n/a - n/a])	
											Cerebrovascular accident (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),		74.0	
											Headache (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Jugular vein thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Lacrimation increased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Nausea (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Superior sagittal sinus thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
	EU-EC-	20/04/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Vomiting (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) Body temperature	[TOZINAMERAN]	Not reported	ICSR
	10008493390	30/04/2021	Sportaneous	Healthcare Professional	Economic	available		Specified	Male	INO	abnormal (n/a - Not Recovered/Not Resolved - Disabling),	(S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSK
											Fatigue (n/a - Not Recovered/Not Resolved - Disabling),			
											Headache (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Not			
											Recovered/Not Resolved - Disabling)			
	EU-EC- 10008473735	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available		Not Specified	Male	No	Arthralgia (2d - Recovered/Resolved -), Chills (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL -	Not reported	ICSR
											Recovered/Resolved -), Headache (2d - Recovered/Resolved	Intramuscular])		
											-), Injection site pain (2d - Recovered/Resolved			
	EU-EC- 10008473924	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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										Pyrexia (4d - Recovered/Resolved	immunisation - n/a - [n/a3mL - Intramuscular])		
EU-EC- 10008474717	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008483813	29/04/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Tinnitus (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Vision blurred (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008483864	29/04/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (3d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[BIOTIN] (C - Supplementation therapy - n/a - [n/a - n/a - n/a]),	ICSR
										Facial paralysis (3d - Recovered/Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Menstrual cycle management - n/a - [n/a - n/a - n/a])	
										Facial spasm (3d - Recovered/Resolved - Other Medically Important Condition),			
										Headache (2985min - Recovered/Resolved			
										Muscle twitching (3030min - Recovered/Resolved			
										Musculoskeletal discomfort (51h - Recovered/Resolved -),			
										Nausea (2985min - Recovered/Resolved -),			
										Piloerection (3d - Recovered/Resolved -)			
EU-EC- 10008485067	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10008485130	29/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10008460364	28/04/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				Area						Hyperhidrosis (n/a - Recovered/Resolved -),	applicable - [n/a - n/a - n/a])		
										Hyperventilation (n/a - Recovered/Resolved			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically			
										Important Condition), Nausea (n/a -			
EU-EC- 10008468787	28/04/2021	Spontaneous		Non	Not	12-17 Voors	Not Specified	Female	No	Recovered/Resolved -) Chills (n/a -	TOZINAMERAN	Not reported	ICSR
10008468787			Healthcare Professional	European	available	Years	Specified			Unknown -),	[TOZINAMERAN] (S - COVID-19		

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				Economic Area						Fatigue (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Migraine (n/a - Unknown -),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Myalgia (n/a -			
EU-EC- 10008455481	27/04/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown -) Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hypersensitivity (n/a - Unknown - Other Medically Important Condition)	-		
EU-EC- 10008456472	27/04/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN]	[ETHINYLESTRADIOL, NORETHISTERONE,	<u>ICSR</u>
			Professional	Area						-), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	FERROUS FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Vomiting (n/a - Recovering/Resolving			
EU-EC- 10008438167	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown - Other Medically Important Condition),			
EU-EC-	25/04/2021	Spontaneous	1114	Non	Not	12-17	Not	Female	No	Wheezing (n/a - Recovering/Resolving - Other Medically Important Condition) Anaphylactoid	TOZINAMERAN	MELATONIN [MELATONIN]	TOOD
10008429112			Professional	Economic Area	available	Years	Specified			reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(C - n/a - n/a - [n/a - 3{DF} - n/a]), METHOTREXATE [METHOTREXATE] (C - n/a - n/a - [n/a - 12.5mg - n/a]), [AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM (CLAVULANATE] (C - n/a - n/a - [7d - 3{DF} - n/a]), [BETAMETHASONE, BETAMETHASONE VALERATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [CALCIPOTRIOL] (C - Rash	
												- n/a - [n/a - 1{DF} - n/a]), [CALCITRIOL] (C - Psoriasis - n/a - [n/a - 1{DF} - n/a]),	
												[CASSIA] (C - n/a - n/a - [n/a - 6{DF} - n/a]),	
												[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 2{DF} - n/a]),	
												[COAL TAR SOLUTION BP, PRECIPITATED SULPHUR BP, SALICYLIC ACID PH. EUR., COAL TAR SOLUTION, SALICYLIC ACID, SULFUR] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[FOLIC ACID] (C - n/a - n/a - [n/a - 1{DF} - n/a]),	
												[METOCLOPRAMIDE] (C -	

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EU-EC- 10008397799		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Decovered/Perchand	applicable - [n/a - n/a -	n/a - n/a - [n/a - 1{DF} - n/a]), [MICONAZOLE NITRATE, HYDROCORTISONE] (C-n/a - n/a - [n/a - n/a - n/a]), [PIZOTIFEN, PIZOTIFEN MALATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE 10N, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, SODIUM CHLORIDE, TO/a - n/a - [n/a - n/a - 1{DF} - n/a]), [SENNA ALEXANDRINA LEAF] (C - n/a - n/a - [n/a - 6{DF} - n/a]) [ACRIVASTINE, DIPHENHYDRAMINE HYDROCHLORIDE, ZINC ACETATE] (C - n/a - n/a - [n/a - n/a - n/a - [n/a - n/a - n/a - n/a - n/a - [n/a - n/a - n/a - n/a - [n/a - n/a	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Intramuscular])	[n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FISH OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [IBUPROFEN, IBUPROFEN LYSINE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10008383998		Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008391075	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008374755	20/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008377751	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10008377754		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Headache (12h - Recovered/Resolved -), Nausea (12h - Recovered/Resolved -), Pain in extremity (12h - Recovered/Resolved -), Vomiting (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10008379252	20/04/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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			Professional	Economic Area						Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])		
EU-EC- 10008359796	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved -), Nausea (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10008360251	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic shock (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008364168	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008331492	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008333553	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008335243	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (16d - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[CASSIA] (C - Faecaloma - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a]),	ICSR
										Diarrhoea (6d - Recovered/Resolved - Other Medically Important Condition),		[OMEPRAZOLE] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a]),	
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		[SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Faecaloma - n/a - [n/a - n/a - n/a])	
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Mobility decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain in extremity (16d - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	15/04/2021	Chantanagus	Haaltheave	Non	Not	12-17	Not	Male	No	Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMEDAN	Not reported	ICCD
10008313721	15/04/2021	Spontaneous	Professional	Non European Economic Area	Not available	Years	Not Specified	Маје	No	Anaphylactic reaction (1d - Recovering/Resolving - Life Threatening),	[TOZINAMERAN] [S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Chest pain (n/a - Unknown - Life Threatening), Hot flush (n/a -	n/a - n/a])		
										Unknown - Life Threatening), Platelet count			
										decreased (n/a - Unknown - Life Threatening), Thrombosis (n/a -			
										Unknown - Life Threatening),			

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										Vomiting (n/a - Unknown - Life Threatening),			
										Wheezing (n/a - Unknown - Life Threatening)			
EU-EC- 10008315283	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), SARS-CoV-2 antibody	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										test (n/a - Unknown -)			
EU-EC- 10008303775	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (1min - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008287937	13/04/2021	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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008287968	13/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Hypersensitivity (5d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN	Not reported	ICSR
EU-EC- 10008292594	13/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LAMOTRIGINE] (C - Seizure - n/a - [n/a - n/a - n/a])	ICSR
										Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008275678	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (1d - Recovered/Resolved - Other Medically Important Condition), Nervousness (1d -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008280814	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	, , ,		
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sleep disorder due to general medical condition, insomnia type (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008247728	09/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymph node pain (n/a - Not Recovered/Not Resolved -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	HUMIRA 80 MG SOLUTION FOR INJECTION IN PRE- FILLED PEN [ADALIMUMAB] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										(n/a - Not Recovered/Not Resolved -)			
EU-EC-	09/04/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Chest pain (n/a -	TOZINAMERAN	Not reported	ICSR

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10008248222			Professional	European Economic Area	available	Years	Specified			Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myopericarditis (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10008248229	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008248258	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008252941	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Headache (n/a - Recovered/Resolved -), Myopericarditis (n/a - Unknown - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008252943	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008235196	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008237832	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown -), Hyperventilation (n/a - Unknown -), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008237922	08/04/2021	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 - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10008237955	08/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Asthma (n/a - Unknown - Other Medically Important Condition), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Migraine (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovered/Resolving - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [DOMPERIDONE] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR

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										Important Condition),			
										Pineal gland cyst (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008243577	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Chest pain (n/a - Unknown -),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
511.50	00/04/2021					10.17				Productive cough (n/a - Unknown -)			1000
EU-EC- 10008245846	08/04/2021	Spontaneous	Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
				Area						Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Vomiting (n/a - Unknown -)			
EU-EC- 10008216424	07/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunistrion - Not	[EPINEPHRINE] (C - Anaphylactic reaction - n/a - [n/a - n/a - n/a])	ICSR
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Lip swelling (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10008218298	07/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition)	CANNABIDIOL [CANNABIDIOL] (S - n/a - Unknown - [n/a - 7mL - n/a]),	Not reported	ICSR
											TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),		
											ZONISAMIDE [ZONISAMIDE] (S - n/a - Unknown - [n/a - 800mg - n/a])		
EU-EC- 10008224932	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown -), Chest pain (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				Alea						Unknown -), Headache (n/a - Unknown -),	applicable - [n/a - n/a - n/a])		
										Myalgia (n/a - Unknown -),			
										Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10008227240	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a]),	ICSR
												[TERBUTALINE SULFATE, TERBUTALINE SULFATE PH. EUR.] (C - Asthma - n/a - [n/a - n/a - n/a])	
EU-EC- 10008206544	06/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Malaise (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown -), Nasal congestion			
										(n/a - Not			

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										Recovered/Not Resolved -)			
EU-EC- 10008209685	06/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	[LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE] (C - n/a - n/a	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		- [n/a - n/a - n/a])	
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vertigo (n/a - Unknown - Other Medically Important Condition),			
										Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008174742	02/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008176129	02/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Illness (n/a - Unknown - Other Medically Important Condition),			
										Myalgia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008158570	01/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[WARFARIN, WARFARIN	
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		SODIUM] (C - Fontan procedure - n/a - [n/a - n/a - n/a])	
EU-EC- 10008160478	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10008143640	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a	Not reported	ICSR
										Decreased appetite (3d - Recovered/Resolved -),	- [n/a3mL - Intramuscular])		
										Pyrexia (3d - Recovered/Resolved -)			
EU-EC- 10008143839	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain (2d - Recovered/Resolved -), Vaccination site joint swelling (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10008144917	31/03/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Hypoaesthesia (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR
			Professional	Economic Area						- Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		

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										Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved - Other Medically Important Condition),			
EU FC	21/02/2021	Carabanan	Non	New	Note	12.17	Net	DA-1-	NI-	Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMEDAN	N.A	Tech
EU-EC- 10008148246	31/03/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fall (n/a - Unknown - Other Medically Important Condition), Head injury (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Condition), Seizure (n/a - Unknown - Other Medically Important Condition),			
										Wound haemorrhage (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008153554	31/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a -			
EU-EC-	30/03/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Blood glucose	TOZINAMERAN		ICSR
10008141445	30,03,2021	Spontaneous	Professional		available	Years	Specified			increased (n/a - Unknown -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Hypopituitarism - n/a - [n/a 8mg - Subcutaneous])	
EU-EC- 10008120530	29/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Migraine (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(C - n/a - n/a - [n/a - n/a - n/a]), [MEDROXYPROGESTERONE ACETATE] (C - n/a - n/a -	ICSR
EU-EC- 10008094065	27/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (2d - Recovered/Resolved -), Paraesthesia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[n/a - n/a - n/a]) [ETHINYLESTRADIOL PROPANESULPHONATE, LEVONORGESTREL, ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - 1{DF} - Oral])	ICSR
EU-EC- 10008082387	26/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10008085488	26/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		Not reported	ICSR
										Pain in extremity (1d - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10008053546	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Multiple sclerosis (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

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										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Sensory loss (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10008056449	24/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (1d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a -	ICSF
										Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	n/a])	
EU-EC- 10008056496	24/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (2d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -		ICSF
											n/a - n/a])	[FAMOTIDINE] (C - Abdominal pain upper - n/a - [n/a - n/a - n/a])	
EU-EC- 10008060186	24/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood urine present (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Urine analysis abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10008040952	23/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dry throat (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
										Influenza (n/a - Unknown - Other Medically Important Condition),	11/a - 11/a])	1ya - 1ya])	
										Nasopharyngitis (n/a - Unknown - Other Medically Important Condition),			
										Sinus disorder (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10008045582	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	Intramuscular])		
										Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Vision blurred (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10008025800		Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	Off label use (n/a -	COMIRNATY [TOZINAMERAN]	CANNABIDIOL [CANNABIDIOL] (C -	ICSR

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			Professional	Area						Product use issue (n/a - Unknown -), Pyrexia (n/a - Unknown -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Epilepsy - n/a - [n/a - 2mL - n/a]), [LAMOTRIGINE] (C - Epilepsy - n/a - [n/a - 100mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [1d - 250mg - n/a]), [SODIUM VALPROATE, VALPROIC ACID] (C - Epilepsy - n/a - [n/a -	
EU-EC- 10007993749	19/03/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	600mg - n/a]) Not reported	ICSR
EU-EC- 10007971661	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (0d - Unknown -), Fatigue (0d - Unknown -), Pain in extremity (0d - Unknown -), Vaccination site pain	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10007951711	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	(0d - Unknown -) Dizziness (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved -) Jeizure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10007929845	15/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysgeusia (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Parosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INSULIN HUMAN [INSULIN HUMAN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pyrexia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10007908508	12/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown -) Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Pain (n/a - Unknown -), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10007892972	11/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (3d - Recovered/Resolved -), Hot flush (3d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10007878771	10/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

i .													
										Recovered/Resolved - Other Medically Important Condition),			
										Malaise (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10007885864	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC- 10007863172	09/03/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ERYTHROMYCIN] (C - Acne - n/a - [n/a - n/a - n/a]), [FLUDROCORTISONE] (C - Postural orthostatic	ICSR
										Asthenia (1d - Recovered/Resolved - Other Medically Important Condition),		tachycardia syndrome - n/a - [n/a - n/a - n/a]), [SODIUM CHLORIDE] (C - Postural orthostatic tachycardia syndrome - n/a	
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		- [n/a - n/a - n/a])	
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Somnolence (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site reaction (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10007865752	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (3d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (7d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10007865757	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (5d - Recovered/Resolved -), Nausea (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10007868826	09/03/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	METHOTREXATE [METHOTREXATE] (C - Arthritis - n/a - [n/a - n/a -	ICSR
				Area						Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - n/a])	n/a]), [INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	
EU-EC- 10007850932	08/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										-), Seizure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10007852893	08/03/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR

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										Dizziness (1d - Recovered/Resolved -),	- n/a - [n/a - n/a - Intramuscular])		
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10007797531	05/03/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
										Dyspnoea (n/a - Unknown - Other Medically Important Condition)	1,74		
EU-EC- 10007786467	04/03/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	04/03/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Fatigue (n/a - Not	TOZINAMERAN	[DESOGESTREL] (C - n/a -	ICSR
10007790604	04/03/2021	Spontaneous		European	available	Years	Specified	remale		Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	n/a - [n/a - n/a - n/a]),	
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		n/a])	
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10007773290	03/03/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Recovered/Resolved -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10007779054	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (3d - Recovered/Resolved -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 30ug - n/a])	Not reported	ICSR
										(3d - Recovered/Resolved -),			
										Myalgia (3d - Recovered/Resolved -), Nausea (3d -			
										Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved			
EU-EC- 10007782357	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthma (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
EU FC	03/03/2021	Chembra	Non	Non	Not	12.47	Not	Male	Ne	Dyspnoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	1{DF} - Intramuscular])	ECITAL ORDAN	Toor
EU-EC- 10007763262	02/03/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (11d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CITALOPRAM HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [DIAZEPAM] (C - Anxiety -	ICSR
										Diarrhoea (3d - Recovered/Resolved - Other Medically Important	, , , , , ,	n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - Nephrotic syndrome - n/a -	

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										Condition),		[n/a - n/a - n/a]),	
										Musculoskeletal stiffness (10d - Recovered/Resolved		[LEVAMISOLE] (C - Nephrotic syndrome - n/a - [n/a - n/a - n/a]),	
										- Other Medically Important Condition),		[OMEPRAZOLE] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a -	
										Nausea (8d - Recovered/Resolved - Other Medically Important Condition),		n/a]), [SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a]),	
										Pyrexia (8d - Recovered/Resolved - Other Medically Important Condition),		[VITAMIN D] (C - Nephrotic syndrome - n/a - [n/a - n/a - n/a])	
										Vaccination site pain (3d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (7d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10007767761	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available		Not Specified	Male	No		TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	·	<u>ICSR</u>
										Arteriospasm coronary (n/a - Recovering/Resolving - Caused/Prolonged Hopticalisation, Other Medically Important Condition),			
										Cardiac discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10007743815	28/02/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	·	<u>ICSR</u>
										Recovered/Not Resolved -), Malaise (n/a - Not	1{DF} - n/a])		
										Recovered/Not Resolved -), Myalgia (n/a - Not			
										Recovered/Not Resolved -), Nausea (n/a - Not			
				_						Recovered/Not Resolved -)			
EU-EC- 10007719432	25/02/2021	Spontaneous		European Economic Area	Not available		Not Specified	Male	No	Asthenia (1d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	·	<u>ICSR</u>
										Chills (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Dizziness postural (1d - Recovered/Resolved - Other Medically Important Condition),			
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (2d -			

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										Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved			
										- Other Medically Important Condition),			
										Unknown - Other Medically Important Condition),			
										(2d - Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0007696878	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
U-EC- 0007696928	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
U-EC- 0007696958	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
U-EC- 0007701374	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICS
EU-EC- 10007684044	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Product use in unapproved indication (n/a - Recovered/Resolved -), Pyrexia (n/a - Unknown -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - n/a])	NOT AVAILABLE (C - n/a - Dose not changed - [n/a - 1g - n/a]), [CHLORAL HYDRATE] (C - n/a - Dose not changed - [n/a - n/a - n/a]), [CLOBAZAM] (C - n/a - Dose not changed - [n/a - 5mg - n/a]), [CLONIDINE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 25ug - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION,	ICS
												HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - Dose not changed - [n/a - n/a - n/a]), [PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - n/a - n/a]),	
												[SALBUTAMOL] (C - n/a - Dose not changed - [n/a - .1mg - n/a])	
U-EC-	18/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[DESOGESTREL] (C -	ICS
1000/65//6/										riospitalisation),			
10007657767										Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Palpitations (n/a -			

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										Caused/Prolonged Hospitalisation)			
EU-EC- 10007633581	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10007612164	14/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved			
EU-EC- 10007584292	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CIRCADIN 2 MG [MELATONIN] (C - n/a - Not applicable - [n/a - 2mg - n/a]), [CLOBAZAM] (C - n/a - Not applicable - [n/a - 10mg - n/a]), [LAMOTRIGINE] (C - n/a - Not applicable - [n/a - 125mg - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - Not	ICSR
EU-EC-	10/02/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Dizziness (n/a -	COMIRNATY	applicable - [n/a - n/a - n/a]) Not reported	ICSR
10007574660			Professional	Economic Area	available	Years				Recovered/Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])		
										Flushing (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10007557615	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Anaphylactic shock (30min - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (30min - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Hypotension (30min			
										Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10007547751	08/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
tne://dan.er										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important			53/F

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										Condition),			
										Tremor (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10007549382	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10007535185	06/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSR
										Dyspnoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Face oedema (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rhinorrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vaccination site pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10007516066	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSR
EU-EC- 10007522203	04/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition)	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10007509084	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Mobility decreased (1d - Unknown -), Pain in extremity (1d	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not		ICSR
										- Unknown -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a])	n/a])	
EU-EC- 10007499072	02/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10007478131	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10007467420	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Peripheral swelling (n/a - Recovered/Resolved - Other Medically Important Condition),	-		
										Pharyngeal swelling (n/a - Recovered/Resolved			

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										- Other Medically Important Condition),			
										Rash (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site movement impairment (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10007458093	28/01/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10007436145	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea exertional (4d - Recovered/Resolved -), Malaise (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Tachycardia (4d - Recovered/Resolved -)			
EU-EC- 10007424301	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC- 10007399721	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Erythema (2d - Recovered/Resolved -), Peripheral swelling (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CLINDAMYCIN, ANHYDROUS BENZOYL PEROXIDE, CLINDAMYCIN, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
EII EC	15/01/2021	Caratana	Nan	Nam	Net	12.17	Net	FI-	NI-	Vaccination site pain (n/a - Unknown -)	TOZINIAMEDANI	Not you saled	TCCD
EU-EC- 10007358701	15/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10007358739	15/01/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Skin haemorrhage (2d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10007346221	14/01/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (1d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
										Injection site pain (1d - Recovered/Resolved -),			
										Muscle spasms (2d - Recovered/Resolved -), Pustule (2d -			
EU-EC-	14/01/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Recovering/Resolving -) Injection site	COMIRNATY	Not reported	ICSR
10007350953	11/01/2021	Sportaneous	Professional	Economic Area	available	Years	Nuorescent	luic		erythema (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Tide reported	1001
										Injection site pain (n/a - Not Recovered/Not Resolved -),	,,,,,,		
										Injection site swelling (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10007342639	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (3d - Recovered/Resolved -), Hypotonia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Paraesthesia (n/a -			
										Not Recovered/Not Resolved -),			
										Recovered/Resolved			

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										Vomiting (3d - Recovered/Resolved -)				
EU-EC- 10007344483	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Nausea (n/a - Unknown -), Nausea (n/a - Unknown -), Sleep disorder (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR	

↑ ↑ ↓ 1 Rows 14001 - 14331 (end)

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