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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- 10010419893	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash erythematous (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010419896	25/10/2021	Spontaneous	Healthcare	Economic	Not available	12-17 Years	Adolescent	Male	No	Orchitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010419949	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Female	No	Asthenia (4d - Recovered/Resolved -), Injection site hypoaesthesia (4d - Recovered/Resolved -), Motor dysfunction (4d - Recovered/Resolved -), Vomiting (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010420014	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Oral herpes (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010420018	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010420020	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved -), Heavy menstrual bleeding (n/a - Recovered/Resolved	[Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010420051	25/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010420144	25/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - 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- 10010420207	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010420326	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010420381	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

											1{DF} - Intramuscular])		
EU-EC- 10010420388	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tonsillitis (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010420389	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Epistaxis (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010420406	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (21d - Recovering/Resolving -)	COMIRNATY	Not reported	ICSR
EU-EC- 10010420839	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Headache (2d - Recovered/Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010420896	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Pericarditis (n/a - Recovering/Resolving Other Medically Important Condition)	COVID-19	Not reported	ICSR
EU-EC- 10010420908	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010421457	25/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Recovering/Resolving -), Heavy menstrual bleeding (19d - Recovered/Resolved -), Intermenstrual bleeding (n/a - Recovered/Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY	NOT AVAILABLE (C - Arrhythmia - Dose not changed - [n/a - 1{DF} - n/a])	ICSR
EU-EC- 10010421741	25/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Fall (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperventilation (n/a - Recovered/Resolved -), Nervousness (n/a - Recovering/Resolving -), Presyncope (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

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										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Shock (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010422595	25/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (2d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, NORGESTIMATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Headache (3d - Recovered/Resolved - Other Medically Important Condition),			
										Lethargy (2d - Recovered/Resolved - Other Medically Important Condition),			
										Pain (3d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010422617	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Unknown -), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Unknown -), Vomiting (1d - Unknown -)			
EU-EC- 10010422944	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Rash (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010422945	25/10/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10010423014	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (2d - Recovered/Resolved -)	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010423198	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010423207	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovering/Resolving -),	COMIRNATY	Not reported	ICSR
										Fatigue (3d - Recovering/Resolving -),			
										Headache (4d - Recovering/Resolving -),			
										Nausea (1d - Recovering/Resolving -), Vomiting (0d -			
EU-EC-	25/10/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Recovering/Resolving -) Injection site pain	COMIRNATY	Not reported	ICSR
10010423661	254275			Economic Area		Years				(2d - Recovered/Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010424162	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	ı*ıa l e	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010424172	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (1d - Recovered/Resolved -)	· •"		
EU-EC- 10010424308	25/10/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

											Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010424396	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10010424474	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										-), Injection site pain (3d - Recovered/Resolved -),			
										Nausea (0d - Recovered/Resolved -), Pyrexia (0d -			
EU-EC- 10010424789	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSF
EU-EC- 10010424837	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Odynophagia (n/a - Unknown -),	- Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Pyrexia (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -)	immunisation - Not applicable - [1d - .3mL - Intramuscular])		
EU-EC- 10010424863	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Unknown -), Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSF
										Pyrexia (n/a - Unknown -), Vaccination site inflammation (n/a - Unknown -)	Intramuscular])		
EU-EC- 10010424870	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ageusia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Anosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010424872	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSF
										Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a -	intramuscular j		
EU-EC-	25/10/2021	Spontaneous	Haaltheara	European	Not available	12-17	Adolescent	Malo	No	Recovering/Resolving - Other Medically Important Condition) Urticaria (n/a - Not	COMIRNATY	Not reported	ICSF
10010424880	23/10/2021	Sportaneous	Professional	Economic Area	Not available	Years	Adolescent	Male	No	Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSF</u>
EU-EC- 10010424981	25/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epilepsy (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010425036	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSF
EU-EC- 10010425049	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSF
										Fatigue (n/a - Recovered/Resolved -), Headache (n/a -	, ,		
										Recovered/Resolved -),			

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										Lymphadenopathy (n/a - Recovered/Resolved -),			
										Nasal congestion (n/a - Recovered/Resolved			
										Palpitations (n/a - Recovered/Resolved			
										- Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10010425062	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010425847	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Headache (1d - Recovered/Resolved -),	[n/a - n/a - n/a])		
										Injection site pain (2d - Recovered/Resolved			
										Lymphadenopathy			
										Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -),			
										Myalgia (1d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved -)			
EU-EC- 10010426094		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Injection site pain (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010427828	25/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Haematoma (4d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010427846	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (30min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Menstruation delayed (8wk - Recovered/Resolved -),			
										Myalgia (4d - Recovered/Resolved -)			
EU-EC- 10010427990	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -),	COVID-19	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Recovering/Resolving -)			
EU-EC- 10010428942	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anal sphincter atony (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Bladder sphincter atony (n/a - Recovered/Resolved - Caused/Prolonged	- n/a])		
										Hospitalisation), Muscular weakness (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myelitis transverse (n/a - Recovered/Resolved			
										- Caused/Prolonged Hospitalisation,			

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										Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010429402	25/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (3d - Recovered/Resolved -), Dizziness (4d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -), Fatigue (4d - Recovering/Resolving -),			
										Influenza (3d - Recovered/Resolved -),			
										Injection site pain (3d - Recovered/Resolved -),			
										Malaise (3d - Recovered/Resolved -),			
										Nausea (3d - Recovering/Resolving -),			
										Pyrexia (4d - Recovered/Resolved -),			
										Vomiting (0d - Recovered/Resolved -)			
EU-EC- 10010430183	25/10/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Cytokine increased (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Hepatic failure (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Multisystem inflammatory syndrome in children (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Polyserositis (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Renal failure (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010432592	25/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Feeling hot (2d - Recovering/Resolving -),			
ELLEC	24/10/2021	Chontanaous	Non	Europoon	Not available	12.17	Not	Famala	No	Pyrexia (2d - Not Recovered/Not Resolved -)	COMTONIATO	Not reported	TOCO
EU-EC- 10010411008		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010411158	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Asthenia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Chest pain (4d - Recovered/Resolved -),			

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										Chills (2d - Recovered/Resolved -),			
										Dyspnoea (3d - Recovered/Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Malaise (5d - Recovered/Resolved -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Palpitations (n/a - Recovering/Resolving -)			
EU-EC- 10010411168	24/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Chills (1d - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (5d - Recovered/Resolved -),			
										Injection site haematoma (1d - Recovered/Resolved -),			
										Injection site pain (1d - Recovered/Resolved -),			
										Myalgia (1d - Recovered/Resolved -)			
EU-EC- 10010411228	24/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010411459	24/10/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Eve pain (11d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[FUSIDIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Eye pruritus (11d - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Eye swelling (11d - Recovered/Resolved -),			
										Rash (11d - Recovered/Resolved -)			
EU-EC- 10010411476	24/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown -), Hypersomnia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Unknown -), Lethargy (n/a - Recovering/Resolving	applicable - [1d - n/a - n/a])		
										Lymph node pain (n/a - Unknown -),			
										Pharyngitis streptococcal (n/a - Unknown -),			
										Swelling face (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important			
				European	Not available	12-17	Not	Female	No	Condition) Asthmatic crisis (n/a	COMIRNATY	Not reported	ICSR
EU-EC- 10010411508	24/10/2021	Spontaneous	Healthcare	Economic		Years	Specified			Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		

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										Hospitalisation), Respiratory tract infection (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010411523	24/10/2021	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),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	CIRCADIN [MELATONIN] (C - Poor quality sleep - n/a - [n/a - n/a - n/a])	ICSR
										Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),	- n/a])		
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),			
EU FC	24/10/2021	Chantonagua	Llog lith cove	Non	Not evalable	12.17	Not	Mala	No	Presyncope (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMEDANI	Net repeated	ICCD
EU-EC- 10010411531	24/10/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010411605	24/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010411621	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[DERMATOPHAGOIDES FARINAE (504), DERMATOPHAGOIDES PTERONYSSINUS (503), ALUMINIUM HYDROXIDE] (C - n/a - n/a - [n/a - n/a - n/a])	-
EU-EC- 10010411632	24/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - n/a - n/a - n/a - n/a), [ATOMOXETINE] (C - n/a - n/a - n/a - n/a - n/a),	ICSR
										Headache (n/a - Not Recovered/Not Resolved -), Injection site		[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
										erythema (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved -),			
EU-EC-	24/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Nausea (n/a - Recovering/Resolving -) Menstrual disorder	COMIRNATY	Not reported	ICSR
10010411697	24/10/2021	Sportalieous	Healthcare Professional	Economic	INOL AVAILABLE	Years	Specified	remale	NO	(n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSK
EU-EC- 10010411724	24/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Malaise (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -)			

EU-EC- 10010411799	24/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010411806	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010411807	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
EU-EC- 10010411809	24/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010411811	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Asthma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 10010408228	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010408723	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
EU-EC- 10010408789	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010408795	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010408805	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICS
EU-EC- 10010408837	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injury (n/a - Recovering/Resolving -), Lip swelling (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -), Swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010408853	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Stevens-Johnson syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), [SULFASALAZINE] (S - Colitis ulcerative - Not applicable - [n/a - 3000mg - Oral])	AZATHIOPRINE [AZATHIOPRINE] (C - Colitis ulcerative - n/a - [n/a - 150mg - Oral]), [MESALAZINE] (C - Colitis ulcerative - n/a - [n/a - 3200mg - Oral])	ICSR
EU-EC- 10010409050	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR

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												- n/a]), [THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010409062	23/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (2mo - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010409101	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10010409180	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10010409221	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ANTICONCEPTIEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
10010409289	23/10/2021	Spontaneous	Non Hea l thcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010409305	23/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
EU-EC- 10010409306	23/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Headache (n/a - Not Recovered/Not Resolved -),			
										(n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not			
										Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not			
EU-EC-	23/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Recovered/Not Resolved -) Arthralgia (n/a -	COMIRNATY	Not reported	ICSF
10010409322			Healthcare Professional	Economic Area		Years	Specified			Recovering/Resolving -), Chills (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not applicable - [n/a -	·	
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -), Hyperpyrexia (n/a -			
										Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (0d - Recovered/Resolved -)			
EU-EC- 10010409344	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Myalgia (3d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010409371	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Dyspnoea (8d - Recovered/Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Recovering/Resolving -),			
										Malaise (8d - Recovered/Resolved -),			
										Pyrexia (8d - Recovered/Resolved -)			
EU-EC- 10010409384	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010409952	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -),	COMIRNATY	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010409955	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010410039	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010410041	23/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Chills (6h - Recovered/Resolved	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional							-), Headache (24h - Recovered/Resolved	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										-), Myalgia (12h - Recovered/Resolved			
										-), Pyrexia (6h - Recovered/Resolved			
										-), Syncope (30min - Recovered/Resolved			
EU-EC-	23/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	-) Amenorrhoea (n/a -	COMIRNATY	Not reported	ICSR

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10010410149			Healthcare Professional	Economic Area		Years	Specified			Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
EU-EC- 10010410162	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal distension (n/a - Not Recovered/Not Resolved -), Breast pain (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[MICONAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Breast swelling (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10010410363	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Myalgia (3d - Recovered/Resolved			
										Pain in extremity (3d - Recovered/Resolved -)			
EU-EC- 10010410490	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (21d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (1d - Recovered/Resolved -), Malaise (1d -	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Resolved -)			
EU-EC- 10010410585	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Recovered/Resolved -), Headache (n/a -	1{DF} - n/a])		
										Recovering/Resolving -), Malaise (3d - Recovered/Resolved			
										-), Myalgia (2d - Recovered/Resolved			
										Nausea (n/a - Recovering/Resolving -)			
EU-EC- 10010410588	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC-	22/10/2021	Chontangous	Non	European	Not available	12.17	Not	Male	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -) Fatique (1d -	applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
10010410837	23/10/2021	Spontaneous	Healthcare Professional	Economic	NOL available	12-17 Years	Specified	Маје	INO	Recovered/Resolved -), Headache (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSK</u>
										Recovering/Resolving -), Malaise (n/a - Recovering/Resolving	[NOT AVAILABLE] (S - Rheumatic disorder -		
										-), Nausea (n/a - Recovering/Resolving	[n/a - n/a - n/a])		
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10010410877	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (288h - Recovered/Resolved -), Headache (288h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Malaise (96h - Recovered/Resolved -),			
										Myalgia (36h -			

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EU-EC- 10010410891	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Fatigue (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -),			
										Myalgia (5d - Recovered/Resolved -),			
										Pyrexia (4d - Recovered/Resolved -)			
EU-EC- 10010396068	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010396101	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010396269	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -), Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -), Musculoskeletal discomfort (n/a - Recovering/Resolving			
EU-EC- 10010396343	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Chest pain (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Fatigue (3d - Recovered/Resolved -),	immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
										Pyrexia (3d - Recovered/Resolved -),			
EU-EC-	22/10/2021	Spontaneous	Hoalthcaro	European	Not available	12-17	Not	Male	No	Vertigo (3d - Recovered/Resolved -) Chest pain (n/a - Not	COMIRNATY	Not reported	ICSR
10010396581	22/10/2021	Sportaneous		Economic Area	NOT available	Years	Specified	Male	No	Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSK
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010396598	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Recovered/Resolved			
EU-EC-	22/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Male	No	-) Chills (n/a - Not	COMIRNATY	Not reported	ICSR

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10010396620			Healthcare Professional	Economic Area		Years	Specified			Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pain	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										(n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not			
										Resolved -), Myalgia (n/a - Not Recovered/Not			
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010396672	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female		Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010397037	22/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010397118	22/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female		Dyskinesia (n/a - Not Recovered/Not Resolved -), Tic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010397169	22/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Feeling abnormal (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
										Mydriasis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010398019	22/10/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Feeling abnormal (1d - Recovered/Resolved - Other Medically Important Condition),	7-27		
										Headache (2d - Recovered/Resolved - Other Medically Important Condition),			
										Malaise (2d - Recovered/Resolved - Other Medically Important Condition),			
										Muscular weakness (2d - Recovered/Resolved			

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										- Other Medically Important Condition),			
										Nausea (2d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010398093	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 0010398479	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
										Hypoaesthesia (n/a - Unknown -), Hypoaesthesia oral	[n/a - n/a - Intramuscular])		
										(n/a - Unknown -), Nausea (n/a -			
										Unknown -), Paraesthesia (n/a - Unknown -),			
										Photophobia (n/a - Unknown -)			
:U-EC- 0010398647	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSE
										Headache (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010398653	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010398744	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (48h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Menstrual disorder (72h - Recovered/Resolved -)			
EU-EC- 10010398854	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved With Sequelae - Life Threatening), Dizziness (n/a - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE,	ICSF
										With Sequelae - Life Threatening), Dyspnoea (n/a - Recovered/Resolved		FLUOXETINE FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										With Sequelae - Life Threatening)		[QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[TOPIRAMATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010398897	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Eye pruritus (n/a - Recovered/Resolved - Other Medically Important Condition),	- n/a])		
										Seasonal allergy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sneezing (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010399561	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged			
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									Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
U-EC- 0010399590	22/10/2021	Spontaneous	Healthcare Professional	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved With Sequelae -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [56d - n/a - n/a])	Not reported	ICS
									Disabling), Ageusia (n/a - Recovered/Resolved With Sequelae -			
									Disabling), Amenorrhoea (n/a - Recovered/Resolved			
									With Sequelae - Disabling), Asthenia (n/a - Recovered/Resolved			
									With Sequelae - Disabling), Balance disorder (n/a			
									Recovered/Resolved With Sequelae - Disabling),			
									Cough (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Decreased appetite (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Dizziness (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Dyspnoea (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Fall (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Fatigue (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Headache (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Hypoacusis (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Hypoaesthesia (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Hypothermia (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Irritability (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Listless (n/a - Recovered/Resolved With Sequelae - Disabling),			
									Lymphadenopathy (n/a - Recovered/Resolved With Sequelae -			
									Disabling), Malaise (n/a - Recovered/Resolved With Sequelae - Disabling)			
									Disabling), Muscular weakness (n/a - Recovered/Resolved			
									With Sequelae - Disabling), Myalgia (n/a - Recovered/Resolved			

Description		11.2022	1.77						rturi	LIIIC LIC	sung i	Срог			
Part												With Sequelae - Disabling),			
Continue and part Cont												(n/a - Recovered/Resolved With Sequelae -			
Detailed												Oropharyngeal pain (n/a - Recovered/Resolved			
Building												Oxygen saturation decreased (n/a -			
Electron												With Sequelae - Disabling),			
Part												Recovered/Resolved With Sequelae -			
Secure Communication Com												circulation (n/a - Recovered/Resolved With Sequelae -			
												-			
EU-EC 22/10/2021 Sportsteenad Non												With Sequelae - Disabling),			
REVERSION 22/10/2021 Spontaneous Non-Recovered Recovered												Recovered/Resolved With Sequelae -			
EI-EC- 1001040193 Sportaneous Non Healthcare Economic Professional Area Not evaluable 12-17 Adelescent Not												Recovered/Resolved With Sequelae -			
EU-EC- 10010399906 22/10/2021 Spontameous Non European Not available 12-17 Addiescent Not Non- Not Non- Not Non- Not Non- Not Non- Not Not Non- Not Not Non- Not N															
ELFEC 10010399896 22/10/2021 Spontaneous Non Hoathcare European Not available 12-17 Addisscent Not Spooffed No More reported CSR More reported												Recovered/Resolved With Sequelae -			
ELEC- 1001/399896 2/10/2021 Spontaneous Non Professional Area Not available Professional Area Not															
Heathcare Professional Profess	EI	LEC-	22/10/2021	Spontaneous	Non	Furonoan	Not available	12-17	Adolescent	Not	No	Recovered/Resolved With Sequelae - Disabling)	COMIDNATY	Not reported	TCSP
EU-EC- 10010400098			22/10/2021	Sportaneous	Healthcare	Economic	NOL available		Adolescent			Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	<u>ICSK</u>
Healthcare Frofessional Area Frofessional Frofessional Area Frofessional Frofessional Frofessional Area Frofessional Frofe												reaction (1d - Recovered/Resolved -)			
Healthcare Professional Profe			22/10/2021	Spontaneous	Healthcare	Economic	Not available			Female	No	- Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010400130 Professional Spontaneous Non Healthcare Professional Spontaneous Not available European Recommic Professional Spontaneous Not available Professional Spontaneous Non European Not available 12-17 Not Female No Addust Pemale No Addust Pemale No Addominal pain (r/a) COMIRNATY Not reported ICSR Pemale No Addominal pain (r/a) COVID-19 (r/a COVID-19 immunisation - Not available 17-17 Not Female No Addust Pemale No Addominal pain (r/a) COVID-19 (r/a COVID-19 immunisation - Not available 17-17 Not Female No Addust Pemale No Addominal pain (r/a) COVID-19 (r/a COVID-19 immunisation - Not available 17-17 Not Female No Addust Pemale No Pemale No Pemale No Pemale No Pemale Not reported ICSR Not reported ICSR Pemale No Pem			22/10/2021	Spontaneous	Healthcare	Economic	Not available			Female	No	(n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
Professional Area Professional Profession			22/10/2021	Spontaneous			Not available		Adult	Female	No	Abdominal pain (n/a	COMIRNATY	Not reported	ICSR
EU-EC- 1010400456 Professional EU-EC- 22/10/2021 Spontaneous Non European Not available Female No COVID-19 (n/a - Recovering/Resolving -), Ovarian cyst (n/a - Recovering/Resolvi												-),	COVID-19 immunisation - Not applicable - [n/a -		
EU-EC- 10010400456 Spontaneous Healthcare Professional European Economic Area European Eu-EC- 22/10/2021 Spontaneous Not available Eu-EC- 22/10/2021 Spontaneous Not available Eu-EC- 22/10/2021 Spontaneous Not available European Not available I2-17 Not Female No CovID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Not available I2-17 Not Not available I2-17 Not Female No Dymenorrhoea (n/a COMIRNATY Not reported ICSR												- Unknown -),	1{DF} - n/a])		
EU-EC- 10010400456												Recovering/Resolving			
EU-EC- 10010400456 Spontaneous Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Recovering Resolving -) Adolescent Female No COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) EU-EC- 22/10/2021 Spontaneous Non European Not available 12-17 Not Female No Dysmenorrhoea (n/a COMIRNATY Not reported ICSR Not reported I												(n/a - Recovering/Resolving			
10010400456 Professional Economic Area Professional Economic Professio												Ovarian cyst (n/a - Recovering/Resolving -)			
Comparison of the Medically Comparison of the Medical of the M			22/10/2021	Spontaneous		Economic	Not available		Adolescent	Female	No	Unknown - Other Medically Important	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR
EU-EC- 22/10/2021 Spontaneous Non European Not available 12-17 Not Female No Dysmenorrhoea (n/a COMIRNATY Not reported ICSR												(n/a - Unknown - Other Medically			
			22/10/2021	Spontaneous			Not available			Female	No			Not reported	ICSR

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			Professional	Area						Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010400964	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010401135	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010401229	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Important Condition) Malaise (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site pain (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10010401460	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Malaise (n/a - Not Recovered/Not Resolved -), Pharyngitis (n/a - Not Recovered/Not Resolved -), Swelling of eyelid (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10010401471	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (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- 10010401472	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010401490	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010401577	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Unknown - Other Medically Important			
EU-EC- 10010401578	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Conjunctival haemorrhage (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CLONAZEPAM] (C - Anxiety, Autism spectrum disorder - n/a - [n/a5mg - n/a]),	ICSR
										Conjunctivitis (n/a - Unknown -), Dizziness (n/a - Recovering/Resolving -),	-	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Anxiety, Autism spectrum disorder - n/a - [n/a - 40mg - n/a]),	
										Fall (n/a - Unknown -), Fatigue (n/a - Unknown -),		[LORAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]),	
										Feeling of body		[QUETIAPINE, QUETIAPINE	

										temperature change (n/a - Unknown -),		FUMARATE] (C - Insomnia - n/a - [n/a -	
										Gait disturbance (n/a		75mg - n/a])	
										- Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving -),			
										Hyperhidrosis (n/a - Unknown -),			
										Muscular weakness (n/a -			
										Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pallor (n/a - Unknown -),			
										Presyncope (n/a - Unknown -),			
										Pyrexia (n/a - Recovered/Resolved -),			
										Stress (n/a - Unknown -),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vertigo (n/a - Unknown -),			
										Vision blurred (n/a - Unknown -),			
										Vomiting (n/a - Recovered/Resolved			
EU-EC- 10010401635	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	-) Collagen disorder (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	IC
										Platelet count decreased (n/a - Unknown - Other Medically Important Condition),	- n/a])		
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										White blood cell count decreased (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010401637	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important		[NAPROXEN, NAPROXEN SODIUM] (C - Heavy menstrual bleeding - n/a - [1d - n/a - n/a]),	IC
										Condition), Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically		[TRANEXAMIC ACID] (C - Heavy menstrual bleeding - n/a - [1d - n/a - n/a])	
EU-EC- 10010401934	22/10/2021	Spontaneous	Non Hea l thcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Dyspnoea (1d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	IC
			Professional	Economic Area		.cars	Specifical			- Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010401943	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (9d - Recovered/Resolved -),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE	Not reported	IC
										Vaccination failure (9d -	MODIFIED) CONCENTRATE FOR DISPERSION FOR		
										Recovered/Resolved - Other Medically Important Condition)	INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a -		
EU EC	22/10/2021	Cnonton	Lloaliba- ··-	Europa	Not available	12.17	Not	Mala	Na	Plood process	.3mL - Intramuscular])	Not reported	10
EU-EC- 10010402176	22/10/2021	Spontaneous	Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (6d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	IC:

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EU-EC-	22/10/2021	Spontaneous	Healthcare	Area	Not available	12-17	Not	Female	No	Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Amenorrhoea (n/a -	COVID-19 - n/a - [n/a - n/a - n/a])	Not reported	ICSR
10010402340	,,		Professional	Economic Area		Years	Specified			Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
EU-EC- 10010402356	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female		Amenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Malaise (11d - Recovered/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	MENQUADFI SOLUTION FOR INJECTION (TETANUS TOXOID, N. MENINGITIDIS GROUP C (STRAIN C11) POLYSACCHARIDE (DE-O-ACETYLATED) CONJUGATED TO TETANUS TOXOID, NEISSERIA MENINGITIDIS GROUP A POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP W-135 POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP W-135 POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP Y POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, TETANUS TOXOID CARRIER PROTEIN) TETANUS TOXOID CARRIER PROTEIN] (C - n/a - n/a - [n/a - n/a	ICSR
EU-EC- 10010402733	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (0d - Recovered/Resolved - Other Medically Important Condition), Seizure (20min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	- n/a]) Not reported	ICSR
EU-EC- 10010403020		Spontaneous	Healthcare	European Economic Area	Not available Not available	12-17 Years	Adolescent			Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Head titubation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Blindness (n/a - Not	COMIRNATY	Not reported Not reported	ICSR
10010403049	-c, 10/2U21	aportianeous	Professional		not available	Years	THEJESTOPE	maic	100	Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	постеропей	<u>.wk</u>

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										Pyrexia (48h - Recovered/Resolved -)	1{DF} - Intramuscular])		
EU-EC- 10010403095	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403099	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site erythema (1d - Recovered/Resolved - Other Medically Important Condition), Lip oedema (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403235	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403264	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403331	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010403427	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403445	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site urticaria (2wk - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10010403449	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403523	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403534	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403535	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403734	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403803	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY	Not reported	ICSR
EU-EC- 10010403809	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010403861	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>

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										Injection site pain (2d - Recovered/Resolved	applicable - [1d - 1{DF} - Intramuscular])		
										Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010403943	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
U-EC- .0010403950	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (8d - Recovered/Resolved -), Pain in extremity (8d - Recovered/Resolved -), Swelling (8d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
U-EC- 0010403954	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Menstruation delayed (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
U-EC- 0010404106	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Child	Male	No	Body temperature decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSI
										Recovered/Resolved - Other Medically Important Condition), Confusional state			
										(n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Recovered/Resolved - Life Threatening),			
										Fear (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Panic attack (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- .0010404511	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epididymitis (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10010404758	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
										Dysgeusia (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -), Injection site			
										inflammation (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
			tics/saw.d							Injection site swelling (n/a - Not			22/

							·	LING LIG		Coport			
										Recovered/Not Resolved -), Injection site warmth (n/a - Not			
										Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),			
										Parosmia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010405069	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site erythema (n/a - Not Recovered/Not Resolved -),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S -	Not reported	ICSR
										Injection site swelling (n/a - Not Recovered/Not Resolved -),	COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])		
										Pain in extremity (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010405500	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010405660	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Headache (1d - Recovered/Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Injection site discomfort (2d - Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved -),			
						10.15				Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 10010405820	22/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010406135	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[ALGELDRATE, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN,	<u>ICSR</u>
										Vaccination site pain (n/a - Recovered/Resolved	applicable - [n/a - n/a - n/a])	LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM	
										Vaccination site		ELATIUS POLLEN, HOLCUS LANATUS POLLEN,	
										Recovered/Resolved		ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS	
												STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA	
												POLLEN, ALNUS GLUTINOSA POLLEN, BETULA VERRUCOSA	
												POLLEN, CORYLUS AVELLANA POLLEN, BETULA VERRUCOSA POLLEN,	
												DERMATOPHAGOIDES FARINAE, DERMATOPHAGOIDES PTERONYSSINUS,	
												PHLEUM PRATENSE POLLEN, POA	

PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ALNUS GLUTINOSA POLLEN, ARRHENATHERUM ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, BETULA
VERRUCOSA POLLEN,
CORYLUS AVELLANA
POLLEN, BULLELIANA POLLEN, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM ELATIUS POLLEN, HOLCUS LANATUS POLLEN ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, PHLEUM POLLEN, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA VERRUCOSA POLLEN, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, PRATENSIS POLLEI LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM ARKHENAI HERUM ELATIUS POLLEN, HOLCUS LANATUS POLLEN, TRITICUM AESTIVUM POLLEN, ANTHOXANTHUM ODORATUM POLLEN, ACPOSTIS AGROSTIS AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, TRITICUM
AESTIVUM, PHLEUM
PRATENSE POLLEN,
POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA POLLEN] (C - n/a - n/a - [1d - n/a - n/a - More in ICSR]), [ALGELDRATE

[ALGELDRATE, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS

STOLONIFERA POLLEN, DACTYLIS
POLLEN, DACTYLIS
GLOMERATA POLLEN, FESTUCA RUBRA
POLLEN, ALNUS
GLUTINOSA POLLEN,
BETULA VERRUCOSA POLLEN, CORYLUS
AVELLANA POLLEN.
BETULA VERRUCOSA
POLLEN, DERMATOPHAGOIDES
FARINAE, DERMATOPHAGOIDES
DERMATOPHAGOIDES
PTERONYSSINUS, PHLEUM PRATENSE
POLLEN, POA
PRATENSIS POLLEN,
LOLIUM PERENNE POLLEN, SECALE
POLLEN, SECALE CEREALE POLLEN,
ALNUS GLUTINOSA
POLLEN, ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, BETULA VERRUCOSA POLLEN,
CORYLUS AVELLANA
POLLEN, PHLEUM
PRATENSE POLLEN, POA PRATENSIS
POLLEN, LOLIUM
PERENNE POLLEN,
SECALE CEREALE POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA POLLEN, PHLEUM
PRATENSE POLLEN,
POA PRATENSIS
POLLEN, LOLIUM PERENNE POLLEN,
SECALE CEREALE
POLLEN,
ADDUENIATHEDLIM
ARRHENATHERUM ELATIUS POLLEN,
ELATIUS POLLEN, HOLCUS LANATUS
ELATIUS POLLEN, HOLCUS LANATUS POLLEN,
ELATIUS POLLEN, HOLCUS LANATUS
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GI OMERATA POLLEN
ELATTUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTI (A BIJBRA
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA VERRUCOSA POLLEN,
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA VERRUCOSA POLLEN, PHLEUM PRATENSE POLLEN, POA
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA VERRUCOSA POLLEN, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN,
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA VERRUCOSA POLLEN, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECAL F
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA VERRUCOSA POLLEN, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN,
ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, BETULA VERRUCOSA POLLEN, PHLEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM
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												- [1d - n/a - n/a]), [DESLORATADINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a -	
EU-EC- 10010406143	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	n/a - [n/a - n/a - n/a]) Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010406338	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (0d - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010406380	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ISOTRETINOIN] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010406381	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU EC	22/10/2021	Chantanagus	Non	Europoon	Not available	12.17	Adalasaant	Mala	No	Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	Intramuscular]) COMIRNATY	Not reported	ICCD
EU-EC- 10010406510	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Recovering/Resolving		Not reported	ICSR
EU-EC- 10010406523	22/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (0d - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10010406566	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Myalgia (n/a - Recovering/Resolving -),	COVID-19	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving -),	immunisation - Not applicable - [0d - n/a - n/a])		
										Vaccination site pain (n/a - Recovering/Resolving -)			
EU-EC- 10010406634	22/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Aphthous ulcer (6d - Recovered/Resolved - Other Medically Important Condition), Genital lesion (6d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	22/10/2021	Chantanagua	Llasthane	Non	Not available	12.17	Not	Famala	No	Recovered/Resolved - Other Medically Important Condition)	COMIDNATY	Not remorted	ICCD
10010406855	22) 1UJ ZUZ I	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperthermia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
EU E2	22/42/5					1.2 :-			ļ	Pyrexia (n/a - Unknown -)	- n/a])	FACTOL C: TT	
EU-EC- 10010407002	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACICLOVIR, ACICLOVIR SODIUM] (C - Antiemetic supportive care - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>

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										Condition), Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[ANTI-D IMMUNOGLOBULIN] (C - Antiemetic supportive care - n/a - [n/a - n/a - n/a])	
										Encephalitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Encephalopathy (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010407306	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in jaw (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- 10010382447	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (15d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Hyperpyrexia (15d - Recovered/Resolved - Other Medically Important Condition),			
										Pruritus (15d - Recovered/Resolved - Other Medically Important Condition),			
										Rash (15d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010382588	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010382948	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyshidrotic eczema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
EU FO	21/10/202	Cnorte	Non	Fire	Not oug 3-1-1-	12.47	Not	Formal	Ne	Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIDNATY	Not rope to d	Icco
EU-EC- 10010383058	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (7d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>

					1		, Itali	LING LIG	ung i	Сроп	1		
										Headache (3d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010383555	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										- Unknown - Other Medically Important Condition)			
EU-EC- 10010383566	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	ENBREL [ETANERCEPT] (C - Psoriasis - n/a - [n/a - n/a - n/a]),	ICSR
										Nausea (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	applicable - [n/a - n/a - Intramuscular])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - Oral])	
										Tremor (3h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010383610	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	- n/a])		
EU-EC- 10010383612	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	- n/a])		
EU-EC- 10010383620	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Unknown - Other Medically Important Condition), Pain in extremity			
										(n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010383866	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness exertional (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[DOCONEXENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),		ESTERS 90, OMEGA-3- ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C - n/a - n/a -),	
										Malaise (n/a - Unknown -),		[VITAMINS NOS] (C - n/a - n/a -)	
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10010384378	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Chills (1d - Recovered/Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Condition), Fatigue (3d - Recovered/Resolved - Other Medically	applicable - [1d - n/a - n/a])		

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District														
Particular Par											Recovered/Resolved - Other Medically			
Part		21/10/2021	Spontaneous		European Economic	Not available			Male	No	Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
Part											Recovering/Resolving - Caused/Prolonged			
Part											Recovering/Resolving - Caused/Prolonged			
R- NC 17/10/2021 Sportmonum Hamiltoner No.											Recovering/Resolving - Caused/Prolonged			
Pearling											Recovering/Resolving - Caused/Prolonged			
Professional European Prof											Recovering/Resolving - Caused/Prolonged Hospitalisation)			
Tributional overdoom Characteristic	EU-EC- 10010384403	21/10/2021	Spontaneous		European Economic	Not available			Female	No	(n/a - Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
EU-EC- 100/10384-431											(n/a - Unknown -), Myocarditis (n/a -	[DIAZEPAM] (S - n/a - Unknown - [n/a - n/a		
EL-EC- 1001.0384431 21/10/2021 Spontaneous Non- Healthcrae Professional Services Burgean Professional Services Recovered Not. Recovered No											- Caused/Prolonged	n/a - Unknown - [n/a - n/a - n/a]),		
EU-EC- 10010384431 21/10/2021 Spontaneous Non Readthcare Frofessional Professional Professional Area Non Recovered/flot Resched -), Weight decreased (r/s - Not Resched -), Weight decreased (r/s - No												HYDROCHLORIDE] (S - n/a - Unknown - [n/a - 20g - n/a]),		
EU-EC- 10010385143 EU-EC-												- Unknown - [n/a -		
EU-EC- 10010385143 EU-EC-	EU-EC- 10010384431	21/10/2021	Spontaneous	Healthcare	European Economic	Not available			Female	No	Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
ELI-EC- 10010385143 Z1/10/2021 Spontaneous Non Heathcare Professional Area ELI-EC- 10010385143 Read-											Recovered/Not Resolved -),			
EU-EC- 10010385143 Spontaneous Resolved - Other Medically Important Condition) EU-EC- 10010385143 Spontaneous Resolved - Other Medically Important Condition EU-EC- 10010385143 Spontaneous Resolved - Other Medically Important Condition European Healthcare Professional Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolving - Life Threatening), Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolv											Recovered/Not Resolved -),			
Heathcare Professional Professi											(n/a - Not Recovered/Not Resolved - Other Medically Important			
Recovering/Resolving - Life Threatening), Headache (46d - Recovering/Resolving - Life Threatening), Malaise (46d - Recovering/Resolving - Life Threatening), Myalgia (46d - Recovering/Resolving - Life Threatening), Myalgia (46d - Recovering/Resolving - Life Threatening), Nausea (46d - Recovering/Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolving - Life Threatening) - Life Threatening, Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening)	EU-EC- 10010385143	21/10/2021	Spontaneous	Healthcare	Economic	Not available			Male	No	Recovering/Resolving - Life Threatening),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSE
Recovering/Resolving - Life Threatening), Malaise (46d - Recovering/Resolving - Life Threatening), Myalgia (46d - Recovering/Resolving - Life Threatening), Nausea (46d - Recovering/Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening)											Recovering/Resolving - Life Threatening),	- n/a])		
Life Threatening), Myalgia (46d - Recovering/Resolving - Life Threatening), Nausea (46d - Recovering/Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening)											Recovering/Resolving - Life Threatening), Malaise (46d -			
Nausea (46d - Recovering/Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening)											- Life Threatening), Myalgia (46d - Recovering/Resolving			
Recovering/Resolving - Life Threatening, Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening)											Nausea (46d - Recovering/Resolving			
Recovering/Resolving - Life Threatening)											Recovering/Resolving - Life Threatening, Other Medically Important			
- Life Threatening)											Recovering/Resolving			
	EU-EC-	21/10/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No		COMIRNATY	Not reported	ICSF

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10010385289			Professional	Economic Area		Years				(n/a - Unknown -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10010385416	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)		Not reported	ICSF
EU-EC- 10010385428	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a - Not Recovered/Not Resolved -), Menstruation delayed (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010385688	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010385713	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010385727	21/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010385728	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - Other Medically Important Condition), Nausea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Unknown - Other Medically Important Condition),	, 3		
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010385765	21/10/2021	Spontaneous	Professional	Economic Area	Not available	12-17 Years	Specified	Female	No	Behaviour disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Personality change (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Psychotic disorder (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010385807	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSF
										Dysstasia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	- n/a])		
										Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Neuropathy peripheral (n/a -			

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										Recovering/Resolving - Caused/Prolonged			
EU-EC- 10010385871	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Dizziness (n/a - Unknown -), Loss of consciousness (1d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Important Condition),			
										Tinnitus (n/a - Unknown -),			
										Visual impairment (n/a - Unknown -)			
EU-EC- 10010385878	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Pyrexia (2d - Recovered/Resolved	immunisation - Not applicable - [1d - n/a - n/a])		
										Vaccination site pain (2d - Recovered/Resolved -)			
EU-EC- 10010385885	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Dyskinesia (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	- n/a])		
										Feeling abnormal (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myoclonus (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU 50	24 (40 (2024					10.17				Somnolence (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation)			1000
EU-EC- 10010385919	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	- n/a])		
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010386187	21/10/2021	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	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),			
										Polymenorrhoea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010386514	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSR
			. 10103301101							-),	Intramuscular])		
					1					Asthenia (n/a -			

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										Recovering/Resolving -), Chest pain (n/a -			
										Recovering/Resolving -),			
										Dizziness (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Malaise (n/a - Recovering/Resolving -),			
										Pain (n/a - Recovering/Resolving -),			
										Pain in extremity (n/a - Recovering/Resolving			
										-), Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10010386698	21/10/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	-) Facial paresis (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						- Caused/Prolonged Hospitalisation), Meningitis (n/a -	COVID-19 immunisation - Not applicable - [n/a - 1{DF} -		
										Recovering/Resolving - Caused/Prolonged Hospitalisation)	Intramuscular])		
EU-EC- 10010387210	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010387997	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Injection site haematoma (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010388159	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010388201	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a -)	ICSR
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged			
EU-EC- 10010389040	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [1d - n/a - n/a])		
U-EC- 0010389061	21/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male		Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Other Medically Important Condition)			
J-EC- 010389068	21/10/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Cold sweat (n/a - Recovered/Resolved -),			
										Dizziness (1d - Recovered/Resolved -),			
										Feeling hot (1d - Recovered/Resolved -),			
										Headache (1d - Recovered/Resolved -),			
										Pallor (1d - Recovered/Resolved -),			
										Pruritus (n/a - Recovered/Resolved -),			
										Urticaria (n/a - Unknown -)			
U-EC- 0010389077	21/10/2021	Spontaneous		Non European Economic Area	Not available	12 - 17 Years	Not Specified	Male		Nausea (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
				Area						Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	applicable - [1d - n/a		
U-EC- 0010389122	21/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male		Body temperature abnormal (2d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Chest pain (2d - Recovered/Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Illness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0010389137	21/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disease recurrence (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Eye disorder (n/a -			

				Economic Area						Recovered/Resolved -),	COVID-19 immunisation - Not		
U-EC- 0010389416	21/10/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling) Mobility decreased (1d -	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	IC
										Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling),			
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling),			
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling),			
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling),			
010389372			Healthcare Professional	Economic Area		Years				(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
I-EC-	21/10/2021	Spontaneous		European	Not available	12-17	Adolescent	Male	No	Pruritus (n/a - Not Recovered/Not Resolved -) Abdominal distension		Not reported	
										Unknown -), Lymphadenopathy (n/a - Unknown -),			
				71160						Condition), Herpes virus infection (n/a -	applicable - [1d - n/a - n/a])		
J-EC- 0010389351	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Herpes ophthalmic (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	
										Rash (n/a - Recovered/Resolved - Other Medically			
										(n/a - Recovered/Resolved - Other Medically Important Condition),			
										Recovered/Resolved - Other Medically Important Condition), Feeling abnormal			
										Important Condition), Dyspnoea (n/a - Recovered/Resolved	applicable - [n/a - n/a - Intramuscular])		
J-EC- 0010389350	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Conjunctival hyperaemia (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	
										-), Seizure (n/a - Recovering/Resolving - Other Medically			
										Recovering/Resolving -), Presyncope (n/a - Recovering/Resolving			
				Economic Area						- Other Medically Important Condition), Fall (n/a -	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
J-EC- 0010389256	21/10/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving -) Bradycardia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	
										Hypoaesthesia (n/a - Recovering/Resolving -), Vision blurred (n/a -			
										Recovering/Resolving -),			

BU-EC- 1/10/2021 Spontaneous Healthcare Frufressional European Professional Euro	Not reported Not reported Not reported	ICSF
EU-EC- 17/10/2021 Spontaneous Healthcare Curpean Professional Marian M	Not reported Not reported	ICSF
ELEC- 10010389444 Professional Professional Professional Professional Professional Area Professional Area Professional Professional Professional Area Professional Area Professional Professional Area Professional Professional Area Professional Professional Area Professional Pr	Not reported	ICSF
Professional Prof	Not reported	ICSF
EU-EC- 10010389452 EU-EC- 10010389452 EU-EC- 10010389452 EU-EC- 10010389713 EU-EC- 10010389713 EU-EC- 10010389724 EU-EC-		
Professional Economic Area Professional Economic Professional Professional Economic Area Professional Profe		
EU-EC- 10010389713 21/10/2021 Spontaneous Professional European Professional Economic Area Professional Economic Professional Professional Economic Professional Profess	Not reported	ICSF
Professional Economic Area Professional Fenomic Area Professional Footation Area Professional Fenomic Area Professional Fenom	Not reported	ICSE
EU-EC- 10010389724 EU-EC-		
EU-EC- 10010389724 EU-EC- 10010389724 EU-FC-		
EU-EC-10010389724 21/10/2021 Spontaneous Non Healthcare Professional Recompliance Professional Recompliance Professional Recompliance Recovering/Resolving Not available Recovering/Resolving Not available Recovering/Resolving Professional Recovering/Resolving Not available Recovering/Resolving Not Recovered/Not Resolved Not Res		
EU-EC- 10010389724 Professional		
EU-EC- 10010389724 21/10/2021 Spontaneous Non Healthcare Professional Healthcare Professional Area Not available 12-17 Years Specified Female Specified Not Resolved -) Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -)		
EU-EC- 10010389724 Spontaneous Non Healthcare Professional Reconsider Area Not available Specified Professional Recovering/Resolving - Not Recovering - Not Recove		
EU-EC- 10010389724 21/10/2021 Spontaneous Non Healthcare Professional Economic Area Not available 12-17 Years Specified Specified No Amenorrhoea (n/a - Not Recovered/Not Resolved -) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not		
	Not reported	ICSF
EU-EC- 10010389726 21/10/2021 Spontaneous Recovered/Not Resolved -) Non Healthcare Professional Professional Realthcare Professional Resolved -) Not available 12-17 Not Specified Specified Resolved -) Not available 12-18 Not Specified Specified Resolved -) Not available Specified Resolved -)	Not reported	ICSF
EU-EC- 10010389782 21/10/2021 Spontaneous Realthcare Professional Professional Realthcare Professional	Not reported	ICSF
EU-EC- 10010389843 21/10/2021 Spontaneous Non Healthcare Professional Recovering/Resolving (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) Non Healthcare Professional Recovering/Resolving (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
Unknown - Other Medically Important Condition), Photophobia (n/a -		
Unknown - Other Medically Important (Condition)		
EU-EC- 10010389851 Spontaneous Realthcare Professional		
Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	Not reported	ICSF
EU-EC- 10010389964 Spontaneous Feathcare 1001038964 Spontane	Not reported	ICSF

										- Caused/Prolonged Hospitalisation)	n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10010390130	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSF
										Headache (n/a - Unknown -),			
										Oropharyngeal pain (n/a - Unknown -),			
										Pain in extremity (n/a - Unknown -), Pyrexia (n/a -			
										Unknown -), Rhinorrhoea (n/a -			
										Unknown -), Suspected COVID-19 (n/a - Unknown - Other Medically			
EU-EC- 10010390189	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Rash macular (n/a - Unknown - Other Medically Important Condition)	- n/a])		
EU-EC- 10010390421	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness postural (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- 10010390539	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010390613	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010390619	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (1wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010390736	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010390869	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Breast pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Palpitations (n/a - Recovering/Resolving -)			
EU-EC- 10010390900	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (6d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (6d - Not Recovered/Not Resolved -),	[[-,4]		
										Influenza like illness (6d - Not Recovered/Not Resolved -),			
										Nausea (6d - Not Recovered/Not Resolved -)			
EU-EC- 10010390921	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition),			

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										Feeling abnormal (n/a - (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important			
										Condition), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Throat irritation (n/a			
										Recovered/Resolved Other Medically			
EU-EC- 10010390923	21/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Arthralgia (n/a - Not Recovered/Not Resolved - Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Disabling),	- n/a])		
										Headache (n/a - Not Recovered/Not Resolved - Disabling),			
										Nausea (n/a - Recovering/Resolving - Disabling), Pyrexia (n/a - Not			
										Recovered/Not Resolved - Disabling)			
EU-EC- 10010390928	21/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeding disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Gamma- glutamyltransferase decreased (n/a - Unknown -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition),			
										Tongue disorder (15d - Recovered/Resolved			
EU EO	24 /4 0 /2024				N	12.17				- Other Medically Important Condition)	COLUMNIATIO		TOOD
EU-EC- 10010390931	21/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),	, 3		
										Hypersomnia (n/a - Unknown -),			
										Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),			
FILES	24/42/555		UPI		No.	10.7				Pain in extremity (n/a - Unknown - Other Medically Important Condition)	COMPANY		100-
EU-EC- 10010391094	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	เซลle	No	Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										Troponin increased (n/a - Not Recovered/Not	and an uscular])		

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										Resolved - Other Medically Important Condition)			
EU-EC- 10010391161	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - Contraception - Drug withdrawn -	Not reported	ICSF
==	21/12/2221			-		10.17					[n/a - 21{DF} - Oral])		
EU-EC- 10010391262	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	маје	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010391273	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010391279	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010391284	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010391291	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10010391372	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010391384	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010391399	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[CODEINE HYDROCHLORIDE, PARACETAMOL, ACETYLSALICYLIC ACID, CODEINE HYDROCHLORIDE, PARACETAMOL, ACETYLSALICYLIC ACID, PARACETAMOL DC 96 %] (C - n/a - n/a - [n/a - n/a - n/a), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - [n/a - [n/a - n/a -	
EU-EC- 10010391401	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dermatitis bullous (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]), [PARACETAMOL] (S - Antipyresis - Drug	Not reported	ICSR
EU-EC- 10010391414	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (2d - Recovered/Resolved -)	Antipyresis - Drug withdrawn - [2d - n/a - Oral]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010391439	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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20-20 20-2												applicable - [1d - .3mL -		
13-00-2013-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-		21/10/2021	Spontaneous	Healthcare	Economic	Not available		Adolescent	Male	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	Not reported	ICSR
2017/07/08 201		21/10/2021	Spontaneous	Healthcare	Economic	Not available		Adolescent	Male	No	Recovered/Resolved -), Influenza like illness (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	Not reported	ICSR
		21/10/2021	Spontaneous	Healthcare	Economic	Not available		Adolescent	Male	No	-) Influenza like illness (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d -	Not reported	ICSR
Important Coop Control Coop Coop Control Coop		21/10/2021	Spontaneous		European	Not available			Male	No	Recovering/Resolving -) Anaphylactic reaction (n/a - Unknown -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
12-17 Not Professional Profe											Important Condition), Cough (n/a - Unknown - Other Medically Important	immunisation - Not applicable - [n/a - n/a		
Professional European New Professional European New Professional European Professional Eur	TH FC	21/10/2021	Constant	I I a like a see	Non	Nata a silabla	12.17	Net	Mala	Nie	Unknown - Other Medically Important Condition)	COMPNADY	Network	TOCO
St. C. Other Medical Continues Commissional Commission		21/10/2021	Spontaneous		European Economic	Not available			Male	No	Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
Professional European Economic Area											Recovering/Resolving - Other Medically Important Condition)			
Hospitalisation), Hospitalisation), Hospitalisation), Hospitalisation), Hospitalisation), Hospitalisation), Hospitalisation), Hospitalisation, Hosp		21/10/2021	Spontaneous		European Economic	Not available			Female	No	Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Liver disorder (n/a - Not Recovered/Not Resolved -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	HANGEKÓBOKUTO] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNOLIA BARK] (C - n/a - n/a - [n/a - n/a - n/a]), [PERILLA FRUTESCENS VAR. CRISPA] (C - n/a	
Complaryngeal pain (n/a - Not Recovered/Not Resolved -) Complaryngeal pain (n/a - Not Recovered/Not Recovered/Not Resolved -) Complaryngeal pain (n/a - Not Recovered/Not Recovered/Resolved Complaryngeal pain (n/a - n/a - n/a) Complaryngeal pain (n/a - Not Pain Compla											Hospitalisation), Malaise (n/a - Not Recovered/Not		n/a]), [PINELLIA TERNATA] (C - n/a - n/a - [n/a -	
U-EC- 0010391676 U-EC- 0010391676 U-EC- 0010391676 U-EC- 0010391676 U-EC- 0010391676 U-EC- 0010391683 U-EC- 0010391684 U-EC- 0010391685 U-EC- 0010391686 U-EC- 001039											Oropharyngeal pain (n/a - Not Recovered/Not		[PORIAE COCOS SCLEROTIUM] (C - n/a - n/a - [n/a - n/a -	
U-EC- 0010391683 U-EC- 0010391683 U-EC- 0010391684 U-EC- 0010391729 U-EC- 0010391682 U-EC- 0010391683 U-EC- 0010391683 U-EC- 0010391684 U-EC- 0010391685 U-EC- 0010391685 U-EC- 0010391685 U-EC- 0010391685 U-EC- 00103916864 U-EC- 00103916864 U-EC- 00103916865 U-E											Recovered/Not		OFFICINALE RHIZOME] (C - n/a -	
EU-EC0010391683 21/10/2021 Spontaneous Non Healthcare Professional Healthcare Professional Area Not available 12-17 Years Not available 12-17 Years Not applicable - [n/a - 1/0F] - Intramuscular]) EU-EC0010391684 21/10/2021 Spontaneous Non Healthcare Professional Recommic Professional Non Healthcare Professional Recommic Recommic Professional Recommic Recomming Re		21/10/2021	Spontaneous		Economic	Not available		Adolescent	Male	No	reaction (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 0010391684 21/10/2021 Spontaneous Non Healthcare Professional Healthcare Professional Supplication - Not available Healthcare Professional Supplication - Not available Healthcare Professional Supplication - Not applicable - Intramuscular]) EU-EC- 0010391729 21/10/2021 Spontaneous Non Healthcare Professional Recommic Area Not available Supplicable - Intramuscular Supplication - Not applicable - Intramuscular Supplication - Not available Supplication - Not applicable - Intramuscular Supplication - Not applicable - In		21/10/2021	Spontaneous	Healthcare	Economic	Not available		Adolescent	Male	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- (0010391729		21/10/2021	Spontaneous	Healthcare	Economic	Not available		Adolescent	Female	No	reaction (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
		21/10/2021	Spontaneous	Healthcare	Economic	Not available		Adolescent	Female	No	Recovered/Resolved -), Dizziness (1mo - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -	Not reported	ICSR
- Not Recovered/Not Resolved -),											Dysmenorrhoea (n/a - Not Recovered/Not			

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										Headache (1mo - Recovered/Resolved -)			
EU-EC- 10010391737	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Immunisation	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
										reaction (6d - Recovered/Resolved -)			
EU-EC- 10010391774	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSF
										Vaccination site pain (n/a - Recovering/Resolving			
EU-EC- 10010391804	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Malaise (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10010391865	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovered/Resolved -)	Intramuscular])	Not reported	ICSR
EU-EC- 10010391968	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN	Not reported	ICSF
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (1d - Recovered/Resolved - Other Medically			
EU-EC- 10010392352	21/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Blood pressure decreased (n/a - Recovered/Resolved -),			
										Bradycardia (n/a - Unknown - Other Medically Important Condition),			
										Cold sweat (n/a - Recovered/Resolved -),			
										Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dry skin (n/a - Recovered/Resolved -),			
										⁻ //			
										Dyspnoea (n/a - Recovered/Resolved -),			

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EU-EC- 10010392716	21/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heart rate decreased (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -) Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010392771	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Other Medically Important Condition) Chest pain (n/a - Recovering/Resolving -), Troponin increased (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010392884	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Injection site inflammation (4d - Recovered/Resolved -), Injection site pain (4d - Recovered/Resolved -), Injection site swelling (4d - Recovered/Resolved -), Menstruation delayed (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010392914	21/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010393319	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Recovered/Resolved - Other Medically Important Condition), Cough (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- 10010393348	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
10010393813		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Diarrhoea (2d - Recovered/Resolved -), Fatigue (4d - Recovered/Resolved -), Hyperpyrexia (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010393872	21/10/2021	Spontaneous	Non Hea l thcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>

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			Professional	Area						Cough (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010394077	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010394316	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Condition) Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a	Not reported	ICSR
EU-EC- 10010394336	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash maculo-papular (n/a - Recovering/Resolving - Other Medically Important Condition)	- Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010394402	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010394405	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving -) Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010394502	21/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angioedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010394556	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Decreased appetite (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010394672	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adult	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010394857	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Presyncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

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EU-EC-	21/10/2021	Spontaneous	Healthcare	Non	Foster CE, Penella	12-17	Adolescent	Female	No	Recovered/Resolved - Other Medically Important Condition) Herpes zoster	MERCAPTOPURINE	Not reported	ICSR
10010394892	21/10/2021	Spontaneous	Professional	European Economic Area	ADV, Davis AL, Arrington AS, Campbell J, Palazzi DL, Varicella-Zoster virus reactivation following SARS-CoV- 2 immunization in two patients with leukemia. Pediatr- Blood-Cancer 2021;68(10):e29191.	Years	Adolescent	remale	NO	ner pes Zoster disseminated (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection reactivation (n/a - Unknown - Caused/Prolonged Hospitalisation), Varicella zoster virus infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	MERCAPTOPURINE (MERCAPTOPURINE (S - Acute ymphocytic leukaemia - Unknown - [n/a - n/a - Unknown]), METHOTREXATE (METHOTREXATE METHOTREXATE METHOTREXATE Caute ymphocytic Leukaemia - Unknown - [n/a - n/a - Unknown]), TOZINAMERAN TOZINAMERAN TOZINAMERAN COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	
10010395458		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010395498	21/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Headache (n/a -	COVID-19 immunisation - Not applicable - [n/a -	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Recovering/Resolving -), Injection site erythema (n/a -	1{DF} - n/a])		
										Recovering/Resolving -), Injection site inflammation (n/a - Recovering/Resolving			
										Injection site pain (n/a - Recovering/Resolving			
										Injection site pruritus (n/a - Recovering/Resolving -),			
										Injection site swelling (n/a - Recovering/Resolving -),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Recovering/Resolving -), Nausea (n/a -			
										Recovering/Resolving -)			
EU-EC- 10010395683	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010368961	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site warmth (1h - Recovered/Resolved -), Presyncope (1h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC-	20/10/2021	Spontaneous	Healthcare	European	Not available	12-17	Not	Male	No	Recovered/Resolved -) Lymphadenopathy	COMIRNATY	Not reported	ICSE
10010369147	25, 15, 2521	Бролалова	Professional	Economic Area		Years	Specified			(n/a - Recovering/Resolving -), Pyrexia (n/a -	[TOZINAMERAN] (S -	nice reported	100.
EU EC	20/10/2021	Ct		F	Niet er eilebie	12.17	Net	F1-	N-	Recovering/Resolving -)		Nat was a d	TOCE
EU-EC- 10010369165	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSF
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010369193	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	SARS-CoV-2 test positive (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										Recovering/Resolving -)	applicable - [n/a - .3mL -		
EU-EC- 10010369322	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICS
EU-EC-	20/10/2021	Spontaneous		European	Not available	12-17	Not	Male	No	Nausea (1d - Recovered/Resolved -) Asthenia (2d -	COMIRNATY	Not reported	ICS
10010369375			Healthcare Professional	Economic Area		Years	Specified			Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])		
EU-EC- 10010369421	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICS
										Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010369651	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -), Insomnia (n/a - Recovering/Resolving -),	COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10010369734	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010369736	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - n/a - n/a - n/a - n/a - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - n/a - n/a - n/a]),	ICS
												[TERBUTALINE SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010369893	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (n/a - Recovered/Resolved -), Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Condition), Pallor (n/a - Recovered/Resolved			
EU-EC- 10010369955	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSI
										Myocarditis (n/a - Not Recovered/Not Resolved - Other	- Intramuscular])		
										Medically Important Condition),			

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ELLEC	20/40/2021	Contrace	Lizabbanea	European	Not available	12.17	Not	Mala	No	Sinus arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY	Not operated	ICCD
EU-EC- 10010370176	20/10/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010370302	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (6min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Anaemia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (44min - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral coldness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral pulse decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Tetany (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010370345	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaemia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Bradycardia (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [n/a - n/a		
										Feeling abnormal (n/a - Recovering/Resolving -)			
EU-EC- 10010370399	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dermatitis bullous (n/a - Unknown - Other Medically Important Condition),	.,, 2,1/		
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Unknown - Other Medically			
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										Important Condition),			
										Skin exfoliation (n/a - Unknown - Other Medically Important			
EU-EC- 10010371428	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Urticaria (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- 10010371558	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary mass (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY	Not reported	ICSR
										Axillary pain (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010371561	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010371598	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010371692	20/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Atrial septal defect (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
			Professional	Area						Recovered/Resolved - Caused/Prolonged Hospitalisation),	Immunisation - n/a - [n/a - n/a - n/a])		
										Transient ischaemic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010371729	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (2d - Recovered/Resolved -),	[.,, = .,, = .,, =],		
										Lymphadenopathy (2d - Recovered/Resolved -),			
										Myalgia (2d - Recovered/Resolved -),			
										Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 10010371879	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling hot (6d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Increased upper airway secretion (6d			
										Recovered/Resolved Other Medically Important Condition),			
										Lethargy (6d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (6d - Recovered/Resolved - Other Medically Important			
										Condition), Suspected COVID-19 (6d -			
										Recovered/Resolved - Other Medically Important Condition),			
										Vaccine breakthrough infection (6d - Recovered/Resolved			
	2011-11					 			ļ	- Other Medically Important Condition)	lanuari		
EU-EC- 10010371881	20/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>

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				Area							COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010372276	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	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
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010372309	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010372366	20/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ear discomfort (n/a - Unknown -), Syncope (1d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010372382	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Costochondritis (n/a - Unknown - Other Medically Important Condition), Hyperaesthesia (n/a	- n/a])		
										- Unknown - Other Medically Important Condition), Inflammation (n/a -			
										Unknown - Other Medically Important Condition)			
EU-EC- 10010372445	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Throat tightness (n/a - Unknown - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Urticaria (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition)	_		
EU-EC- 10010372471	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Chills (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - Other Medically Important Condition),	١,٧٥١		
										Liver function test increased (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010372479	20/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010372489	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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Bit										Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important			
Special Content Special Co										Recovered/Resolved - Other Medically Important			
Part										Recovered/Resolved - Other Medically Important			
Pode										Recovered/Resolved - Other Medically			
Net Reconscioling Net	EU-EC- 10010372491	20/10/2021	Spontaneous		European Economic	Not available		Male	No	upper (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
BEU-6C- 100.1372494 20/10/2021 Sportaneous Residence Professional Residence Professional Residence Professional Residence Resi										Not Recovered/Not Resolved - Other Medically Important	- n/a])		
ELEC. 2010/2021 Sportlaneous Non Healthcare Sungapara Professional Economic Pr										Recovered/Not Resolved -),			
2010/2021 Sportaneous Non Not available Septimal Septi										Recovered/Not			
EU-EC- 100.10372595 201.0/2021 Sportaneous Healthcare Non Professonal Committee Area Not available 12-17 Not Years EU-EC- 100.10372595 201.0/2021 Sportaneous Professonal Professonal Committee Area Not available 12-17 Not Available Not	EU-EC- 10010372494	20/10/2021	Spontaneous	Healthcare	European Economic	Not available		Female	No	Eye pain (n/a - Unknown - Disabling, Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
EU-EC- 100.10372293 20/10/2021 Spontaneous Healthcare Recommendation Professional European Professional European Professional European Professional European Recommendation Professional European Recommendation Recomme										Recovered/Not Resolved - Disabling, Other Medically Important	- n/a])		
EU-EC- 100 103727805 20/10/2021 Spontaneous Healthcare Professional Condition) EU-EC- 100 103727805 20/10/2021 Spontaneous Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthcare Professional Condition EU-EC- 100 103727806 20/10/2021 Spontaneous Non Healthca										(n/a - Unknown - Disabling, Other Medically Important			
Professional European Economic Area Professional European Not available Economic Area Professional European Economic Area Professional European Economic Area Professional European Not available Economic Area Professional European Economic Area Professional European Economic Area Professional European Ec										Unknown - Disabling, Other Medically			
EU-EC- 10010372788 20/10/2021 Spontaneous Healthcare European Not available 12-17 Adolescent Female No COMPAN Confidency Company C	EU-EC- 10010372505	20/10/2021	Spontaneous		European Economic	Not available		Female	No	upper (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
EU-EC- 10010372788 Professional European Professional Economic Area Adolescent Female										Caused/Prolonged Hospitalisation), Headache (n/a -			
EU-EC- 10010372788 20/10/2021 Spontaneous Healthcare Professional Economic Area Not available 12-17 Years Professional Professio										-),			
EU-EC- 10010372893 20/10/2021 Spontaneous Professional Professional Real Professional Real Recovered/Not Resolved - Other Medically Important Condition). Non Healthcare Professional Real Recovered/Not Resolved - Other Medically Important Condition). Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness	EU-EC- 10010372788	20/10/2021	Spontaneous		Economic	Not available	Adolescent	Female	No	Unknown -) COVID-19 (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSF
EU-EC-10010372893 20/10/2021 Spontaneous Spontaneous Spontaneous Spontaneous Non Healthcare Professional Feature Professional Feature Professional Spontaneous Non Healthcare Professional N										Vaccination failure (n/a - Unknown - Other Medically	Indumoscalarj)		
Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness	EU-EC- 10010372893	20/10/2021	Spontaneous	Healthcare	European Economic	Not available		Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness										Recovered/Not Resolved - Other Medically Important	- n/a])		
										Recovered/Not Resolved - Other Medically Important			
										Muscular weakness (n/a - Not			

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EU-EC- 10010372906	20/10/2021	Spontaneous	Healthcare	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 - [1d - n/a - n/a])	Not reported	ICSR
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaginal haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010372950	20/10/2021	Spontaneous	Non Healthcare Professional	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]	Not reported	ICSF
										Axillary pain (n/a - Unknown - Other Medically Important Condition),	1,40])		
										Headache (1d - Recovered/Resolved - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site swelling (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010372959	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSF
EU-EC-	20/10/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Formula	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition) Dysmenorrhoea (3d -	- Intramuscular]) COMIRNATY	COMIRNATY	ICSF
10010373440	20/10/2021	Sportaneous	Healthcare Professional	Economic	INOL available	Years	Adojestent	remaje	No	Not Recovered/Not Resolved -), Malaise (3d - Not Recovered/Not	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[TOZINAMERAN] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSF
EU-EC- 10010374356	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Migraine (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10010375027	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010375594	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (6d - Recovering/Resolving -), Headache (6d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF

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										Recovering/Resolving			
										Nausea (6d - Recovering/Resolving			
EU-EC- 10010376008	20/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Shock (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010376012	20/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Headache (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10010376039	20/10/2021	Spontaneous	Healthcare	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])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	7,23		
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010376117	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010376118	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Brain herniation (n/a - Unknown - Other Medically Important Condition), Brain oedema (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]	Not reported	ICSR
										Unknown - Other Medically Important Condition), Circulatory collapse	, ,,,u ₁)		
										(n/a - Fatal - Results in Death, Other Medically Important Condition),			

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										Gastric disorder (n/a - Unknown -),			
										Gastric ulcer (n/a - Unknown - Other Medically Important Condition),			
										Gastritis erosive (n/a - Unknown - Other Medically Important Condition),			
										Myocardial bridging (n/a - Unknown - Other Medically Important Condition),			
										Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition),			
										Pulmonary congestion (n/a - Unknown - Other Medically Important Condition),			
										Pulmonary oedema (n/a - Unknown - Other Medically Important Condition),			
										Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition)			
EU-EC- 10010376134	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (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	<u>ICSR</u>
EU EO	20/40/2024		11. 10.			42.47	Additional	F I		Urticaria (n/a - Unknown - Other Medically Important Condition)	COMPNATA	Newscaled	TOOD
EU-EC- 10010376188	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010376855		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	<u>ICSR</u>
										Fall (n/a - Recovered/Resolved -), Heart rate decreased	- n/a])		
										(n/a - Recovered/Resolved -),			
										Loose tooth (n/a - Recovered/Resolved -),			
										Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved -),			
										Tooth socket haemorrhage (n/a -			
										Recovered/Resolved -)			
EU-EC- 10010376887	20/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
	20/10/2021	Spontaneous Spontaneous	Professional	European Economic	Not available Not available	Years			No No	-) Bell's palsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported Not reported	ICSR ICSR
10010376887 EU-EC-	20/10/2021		Professional Non Healthcare	European Economic Area Non European Economic		Years	Specified Not			-) Bell's palsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Cough (n/a - Not Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not		

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										Gastrooesophageal reflux disease (n/a - Unknown -), Headache (n/a - Unknown -), Pain in extremity (16h - Recovered/Resolved -), Productive cough (n/a - Unknown -), Rhinitis allergic (n/a - Unknown -), Somnolence (n/a - Unknown -), Wheezing (n/a - Unknown -)			
	0010376925		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified		Cyanosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN] (S - [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
1	0010376939		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Unknown -), Pallor (n/a - Unknown -), Vision blurred (1d - Recovered/Resolved - Other Medically Important Condition), Dysphonia (n/a - Note of the Medically Important Condition)	TOZINAMERAN] (S - [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
	0010377122			Healthcare Professional	Economic Area		Years	Specified		Recovered/Not Resolved -), Nasal congestion (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Respiratory symptom (n/a - Not Recovered/Not Resolved -), Rhinitis (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
	U-EC- 0010377541	20/10/2021	Spontaneous		European	Not available	12-17 Years	Not Specified	Female	Blindness (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia oral (n/a - Unknown - Other Medically	TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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											Important Condition),			
											Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Vision blurred (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10010377608	20/10/2021	Spontaneous	Healthcare	Economic	Not available	12 - 17 Years	Adolescent	Male		Angina pectoris (n/a	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
				Professional	Area						Recovering/Resolving -),	Immunisation - n/a - [n/a - n/a - n/a])		
											Aspartate aminotransferase increased (n/a - Recovering/Resolving -),			
											Blood creatine phosphokinase increased (n/a - Recovering/Resolving -),			
											Dizziness (n/a - Recovering/Resolving -),			
											Myalgia (n/a - Recovering/Resolving -),			
											Nausea (n/a - Recovering/Resolving -),			
											Peripheral vascular disorder (n/a - Recovering/Resolving -),			
											Vomiting (n/a - Recovering/Resolving -)			
	EU-EC- 10010377642	20/10/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male		Angina pectoris (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
											Aspartate aminotransferase increased (n/a - Recovering/Resolving -),	- · · · · · · · ·		
											Blood creatine phosphokinase increased (n/a - Recovering/Resolving -),			
											Dizziness (n/a - Recovering/Resolving -),			
											Myalgia (n/a - Recovering/Resolving -),			
											Nausea (n/a - Recovering/Resolving -),			
											Peripheral vascular disorder (n/a - Recovering/Resolving -),			
											Vomiting (n/a - Recovering/Resolving -)			
	EU-EC- 10010377766	20/10/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a	COMIRNATY [TOZINAMERAN] (S -	[BUDESONIDE] (C - Asthma - n/a - [n/a -	<u>ICSR</u>
					Area						Hospitalisation),	n/a - n/a - [1d - n/a - Intramuscular])	n/a - Respiratory (inhalation)]), [NAPROXEN,	
											Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		NAPROXEN SODIUM] (C - Pain - n/a - [n/a - n/a - Oral]),	
											Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		[PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [SALBUTAMOL,	
											Dizziness (n/a - Recovering/Resolving - Caused/Prolonged		SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory	
											Hospitalisation), Fall (n/a -		(inhalation)])	
											Recovering/Resolving - Caused/Prolonged Hospitalisation),			

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										Gait disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscle tightness (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Musculoskeletal pain (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010378316	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378346	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Inappropriate schedule of product administration (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Intramuscular])		
EU-EC- 10010378366	20/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Fall (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010378432	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haemorrhagic ovarian cyst (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010378561	20/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional							-), Influenza like illness (n/a -	COVID-19 immunisation - Not applicable - [n/a - 1{DF} -		
EU-EC-	20/10/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Recovered/Resolved -) Influenza like illness	Intramuscular]) COMIRNATY	Not reported	ICSR
10010378578	_0, 10, 2021		Healthcare	Economic Area		Years		. Total		(1d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -		
										Vaccination site pain (1d - Recovered/Resolved -)	1{DF} - Intramuscular])		
EU-EC- 10010378605	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

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										Rash macular (n/a - Recovered/Resolved -)			
EU-EC- 10010378700	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378709	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eye pruritus (24h - Recovering/Resolving -), Eyelid oedema (24h - Recovering/Resolving -), Ocular hyperaemia (24h - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010378782	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fall (n/a - Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378854	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adult	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378879	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378888	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adult	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378912	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378913	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010378931	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash vesicular (n/a - Recovering/Resolving -)	COMIRNATY	Not reported	ICSR
EU-EC- 10010378932	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (2wk - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378960	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010378978	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10010378996	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Child	Male	No	Influenza like illness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010378997	20/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Child	Male	No	Influenza like illness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010379086	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hyperhidrosis (1d - Recovered/Resolved -), Vision blurred (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

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EU-EC- 10010379088	20/10/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010379145	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acquired phimosis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10010379146	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010379147	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Recovering/Resolving -)	immunisation - Not applicable - [n/a - 1{DF} - n/a]),	Not reported	<u>ICSR</u>
											[ETHINYLESTRADIOL, LEVONORGESTREL] (S - n/a - Drug withdrawn - [n/a - n/a - n/a])		
EU-EC- 10010379156	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Not Resolved -), Nausea (n/a - Not			
EU-EC-	20/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Recovered/Not Resolved -) Body temperature	COMIRNATY	Not reported	ICSR
10010379184	20/10/2021	Sportarieous	Healthcare Professional	Economic	Not available	Years	Specified	remale	NO	increased (2d - Recovered/Resolved -), Chills (2d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICON</u>
										Fatigue (5d - Recovered/Resolved -),			
										Headache (2d - Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -)			
EU-EC- 10010379249	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intraventricular haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10010379253	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Unknown -), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010379302	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Diarrhoea (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Loss of personal independence in daily activities (4d - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -)			
EU-EC-	20/10/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Syncope (n/a -	TOZINAMERAN	Not reported	ICSR

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10010379338			Professional	European Economic Area		Years	Specified			Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a		
EU-EC- 10010379345	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Hospitalisation), Immunisation (n/a -			
										Unknown -), Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Off label use (n/a - Unknown -),			
										Respiration abnormal			
EU-EC-	20/10/2021	Spontaneous	1114	Non	Not available	12.17	Not	Female	No	Recovered/Resolved - Caused/Prolonged Hospitalisation) Blood pressure	COMIRNATY	Networked	TOST
10010379353	20/10/2021	Sportalieous	Professional	Non European Economic Area	Not available	12-17 Years	Specified	Temale	No	decreased (0d - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSF
										Dizziness (0d - Recovered/Resolved - Other Medically Important Condition),	and an ascalar jy		
										Hypoaesthesia (0d - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (0d - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (0d - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (0d - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010380176	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICS
										Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	- Intramuscular])		
										Erythema multiforme (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			
										Condition), Headache (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
ttps://dap.e	ma auran	 	tice/saw.d							Urine ketone body			57/7

										present (n/a - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10010380189	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Allergy to vaccine (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramoscalary		
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Ocular hyperaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Photophobia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Thrombocytopenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Visual impairment (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010380210	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site swelling (n/a - Recovered/Resolved -), Polymenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010380230	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Menstrual discomfort (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- 10010380474	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Condition), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010381144	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010381477	20/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
EU-EC-	20/10/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Polymenorrhoea	Intramuscular]) COMIRNATY	Not reported	ICSR

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10010381569			Professional	Economic Area		Years				(37d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -		
EU-EC- 10010381645	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (34d - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010381773	20/10/2021	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 - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010381797	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010381831	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Important Condition Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010381898	20/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Unknown - Other Medically Important Condition), Asphyxia (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dyslalia (n/a - Unknown -), Dysstasia (n/a - Unknown -), Fall (n/a - Unknown -), Rash macular (n/a - Unknown -), Rash macular (n/a - Unknown -), Vaccination site pruritus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010382190	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

Model March Model Mode	 						_			applicable - [n/a - 1{DF} - n/a])		
Part	19/10/2021	Spontaneous	Healthcare	Economic	Not available		Female	No	irregular (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
1941-1979 Spring rough Spring	19/10/2021	Spontaneous	Healthcare	Economic	Not available		Male	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICS
U-EC- 00.10356652 19/10/2021 Spontaneous Non Healthcare Economic Professional Avea Not available 12-17 Not Years Specified Female No Chest pain (n/a - Not Recovered/Not Resolved -), Impection site enflammation (n/a - Not Recovered/Not Resolved -), Impection site enflammation (n/a - Not Recovered/Not Resolved -), Impection site enflammation (n/a - Not Recovered/Not Resolved -), Impection site enflammation (n/a - Not Recovered/Not Resolved -), Impection site enflammation (n/a - Not Recovered/Not Resolved -), Impection site enflammation (n/a - Not Recovered/Not Resolved -), Impection site pain (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolve	19/10/2021	Spontaneous	Healthcare	Economic	Not available		Female	No	Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Dyspnoea (1d - Recovered/Resolved -), Erythema (2d - Recovered/Resolved -), Eye swelling (3d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Influenza like illness (2d - Recovered/Resolved -), Lip swelling (3d - Recovered/Resolved -), Lip swelling (3d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	
Healthcare Professional Area P									Recovered/Resolved -), Pyrexia (1d -			
Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)	19/10/2021	Spontaneous	Healthcare	Economic	Not available		Female	No	Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovered/Not Resolved -), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	IG

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10010356896			Healthcare Professional	Economic Area		Years	Specified			Recovering/Resolving -), Tremor (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a -		
EU-EC- 10010356904	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Phlebitis superficial (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010357002	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Tinnitus (22d - Recovered/Resolved -), Vertigo (22d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010357027	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (n/a - Not Recovered/Not Resolved -), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010357143	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Decreased appetite (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010357216	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010357219	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010357404	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - - Recovering/Resolving - Caused/Prolonged Hospitalisation), Migraine (n/a - Recovering/Resolving - - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010357427	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010357430	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010357433	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010357596	19/10/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menometrorrhagia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [LYNESTRENOL] (S - n/a - Drug withdrawn	Not reported	ICSR
EU-EC- 10010357773	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Unknown - Other Medically Important Condition)	- [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [SODIUM VALPROJE ACID] (S - Epilepsy - Unknown -	Not reported	ICSR

											[n/a - n/a - Unknown])		
EU-EC- 10010358277	19/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Disabling), Infectious mononucleosis (n/a - Not Recovered/Not Resolved - Disabling)		Not reported	ICSR
EU-EC- 10010358282	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash erythematous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	ICSR
EU-EC- 10010358434	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Altered state of consciousness (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Clonic convulsion (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Depressed level of consciousness (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Depressed level of consciousness (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Encephalopathy (402h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMINATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010358500	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Interchange of vaccine products (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown - More in ICSR]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX- 024414)] (S - COVID- 19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10010358950	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010358995	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Medically Important	applicable - [n/a - n/a		
EU-EC- 10010358997	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Headache (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010359028	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - Other Medically Important Condition) Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
EU-EC- 10010359401	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Heart rate increased (n/a - Not Recovered/Not	applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Resolved -), Nausea (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Syncope (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010359814	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (5s - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC- 10010359872	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
			Troressional	7,100						Fatigue (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Recovered/Resolved -),			
										Injection site pain (2d - Recovered/Resolved -),			
										Malaise (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved -)			
EU-EC- 10010359939	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (12h - Recovered/Resolved -),	applicable - [n/a - 1{DF} - Intramuscular])		
										Pain in extremity (2d - Recovered/Resolved -),			
										Pain in extremity (3d - Recovered/Resolved			
										-), Puncture site			
										oedema (2d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10010359980	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [21d - .3mL -	Not reported	ICSR
										Syncope (1min - Recovered/Resolved - Other Medically Important Condition),	Intramuscular])		
										Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition)			
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EU-EC- 10010360127	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010360356	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010360607	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain of skin (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin discolouration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin discolouration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin exfoliation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin lesion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010360695	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Medically Important Condition) Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Puncture site pain (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010360936	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010361003	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010361110	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010361150	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Swelling of eyelid (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010361193		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010361436	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S -	Not reported	ICSR

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										Lymph node pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	n/a - n/a - [n/a - .3mL - Intramuscular])		
										Lymphadenopathy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	19/10/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) COVID-19 (n/a -	COMIRNATY	Not reported	ICSR
10010361860				Economic Area		Years				Unknown - Other Medically Important Condition), Vaccination failure	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	·	
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010362271	19/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Chills (n/a - Recovered/Resolved -),	- n/a])		
										Dizziness (n/a - Recovered/Resolved -), Hyperhidrosis (n/a -			
										Recovered/Resolved -), Muscular weakness			
										(n/a - Recovered/Resolved -)			
EU-EC- 10010362275	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010362302	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petit mal epilepsy (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- 10010362304	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010362322	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (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
										Presyncope (n/a - Recovered/Resolved -)			
EU-EC- 10010362325	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	- n/a])		
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010362347	19/10/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Recovered/Not Resolved -),	COVID-19 immunisation - Not		

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										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not	applicable - [n/a - n/a - n/a])		
EU-EC- 10010362352	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Resolved -) COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
EU-EC- 10010362392	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved - Other Medically Important Condition), Urticaria (1d -			
										Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	19/10/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Syncope (n/a -	COMIRNATY	Not reported	ICSR
10010362393	,,			European Economic Area		Years	Specified			Recovered/Resolved - Other Medically Important Condition), Tachycardia (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved			
EU-EC- 10010362405	19/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Analgesic drug level (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - [n/a - 500mg - n/a]),	ICSR
										Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	- n/a])	[AMYLMETACRESOL, 2,4 DICHLOROBENZYL ALCOHOL, LIDOCAINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1500mg - n/a]),	
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not		[BENZYDAMINE HYDROCHLORIDE, BENZYDAMINE HYDROCHLORIDE, BENZOCAINE] (C - n/a - n/a - n/a - n/a - n/a),	
										Recovered/Not Resolved - Other Medically Important Condition),		[PARACETAMOL] (C - n/a - n/a - [n/a - 1500mg - n/a])	
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pharyngeal swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Photopsia (n/a - Recovering/Resolving - Other Medically Important Condition),			
EU-EC-	19/10/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition) Myocarditis (n/a -	COMIRNATY	Not reported	ICSR
10010362428	15, 10, 2021	Sportuneous	Professional	European Economic Area		Years	Specified	riule	140	Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	not reported	<u></u>
EU-EC- 10010362432	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	19/10/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Abdominal pain (n/a		[CHLORPHENAMINE	<u>ICSR</u>

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10010362443			Healthcare Professional	European Economic Area		Years	Specified			- Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Dehydration (n/a -	COVID-19	MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, IBUPROFEN, IBUPROFEN] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Not Recovered/Not Resolved - Other Medically Important Condition),		[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
										Diarrhoea (n/a - Not Recovered/Not Resolved -),			
										Ear disorder (n/a - Not Recovered/Not Resolved -),			
										Ear pain (n/a - Not Recovered/Not Resolved -),			
										Eating disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lethargy (n/a - Not Recovered/Not Resolved -),			
										Ocular hyperaemia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Rash (2d - Recovered/Resolved -),			
EU-EC-	19/10/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Vomiting (n/a - Not Recovered/Not Resolved -) Myocarditis (n/a -	COMIRNATY	Not reported	ICSR
10010362449	15,10,2021	Sportaneous		European Economic Area	The dvallage	Years	Specified	Traic .		Not Recovered/Not Resolved - Other Medically Important Condition), Troponin I increased	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Петерогеа	<u>ICON</u>
										(n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010362450	19/10/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Compartment syndrome (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010362741	19/10/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Chi l d	Female	No	Unknown -) Arthralgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						Resolved -), Chills (n/a - Recovered/Resolved -),	COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])		
										Hallucination (n/a - Recovered/Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Lacrimation increased (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10010362976	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010362981	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Pericarditis (n/a - Unknown - Other Medically Important Condition)	- n/a])		

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EU-EC- 10010363072	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaesthesia (1d - Recovered/Resolved -), Muscular weakness (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010363218	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Injection site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010363493	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (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- 10010363509	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Discomfort (n/a - Recovered/Resolved -), Electrocardiogram abnormal (n/a - Unknown -), Infection (n/a - Recovering/Resolving -), Malaise (n/a - Unknown -), Musculoskeletal stiffness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	10/10/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Painful respiration (n/a - Recovered/Resolved -) Dizziness (n/a - Not	TOZINAMERAN	Not reported	ICSR
10010363523			Healthcare Professional	European		Years	Specified			Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10010363527	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010363530	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Pneumothorax (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010363536	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010363767		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (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- 10010363770	19/10/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Economic						- Other Medically	immunisation - Not		
EU-EC- 10010363784	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Acute disseminated encephalomyelitis (n/a -	applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
				Area						Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										CSF cell count increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										CSF immunoglobulin increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										CSF protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Central nervous system lesion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Feeling abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Gait disturbance (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										White matter lesion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010363813	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Lymphadenopathy (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010364197		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010364244	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSE
										Monoparesis (3d - Not Recovered/Not			

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										Resolved -), Paraesthesia (3d - Not Recovered/Not Resolved -)			
EU-EC- 10010364526	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ETHINYLESTRADIOL, GESTODENE] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC- 10010364671	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10010364925	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010364942	19/10/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -)	TOZINAMERAN	Not reported	ICSR
EU-EC- 10010364967	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Dysgeusia (n/a - Unknown - Other Medically Important Condition), Fatigue (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 - Not Recovered/Not Resolved - Other Medically Important Condition), Hypersomnia (n/a - Unknown - Other Medically Important Condition),			
										Oropharyngeal pain (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010364982	19/10/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010365047	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Condition) Arthralgia (n/a - Recovered/Resolved -), Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010365058	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010365069	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Malaise (2h - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010365113	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a -	COMIRNATY	Not reported	ICSR

										Recovering/Resolving			
EU-EC- 10010365177	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (n/a - Recovering/Resolving -), Anosmia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010365201	19/10/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Back pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Immunisation reaction (n/a - Recovering/Resolving -)	immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010365207	19/10/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (21d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR



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