Line Listing Report Time run: 30/11/2022 12:33:34

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)	Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSF Forn
EU-EC- 10009700420	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -),	COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSF
										Fatigue (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Myalgia (n/a - Recovering/Resolving -)			
EU-EC- 10009700424	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009700425	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (4d - Recovered/Resolved -), Fatigue (4d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]),	ICSE
										Recovered/Resolved -), Headache (4d - Recovered/Resolved	1{DF} - n/a])	[MELATONIN] (C - Insomnia - n/a - [n/a - n/a - Oral]), [MOMETASONE FUROATE] (C -	
										-), Nausea (4d - Recovered/Resolved -),		Eczema - n/a - [n/a - n/a - Cutaneous]), [MOMETASONE FUROATE] (C - Rhinitis allergic - n/a - [n/a -	
										Vomiting (4d - Recovered/Resolved		n/a - Nasal]), [NAPROXEN] (C - Myalgia - n/a	
EU-EC- 10009700430	16/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Menstrual disorder (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	- [n/a - n/a - Oral]) Not reported	ICSR
EU-EC- 10009700433	16/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10009700434	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site haemorrhage (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009700435	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009700436	16/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700437	16/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
EU-EC- 10009700438	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700443	16/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	[ADAPALENE, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009700446	16/08/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

0.11.2022 1	2.48							Run	Line I	_isting Report			
			Professional	Area						Pyrexia (10d - Recovered/Resolved	COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])		
EU-EC- 10009700449	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (1d - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ISOTRETINOIN] (C - Pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009700451	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009700452	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	[CIPROFLOXACIN HYDROCHLORIDE, DEXAMETHASONE, DEXAMETHASONE, CIPROFLOXACIN] (C - Ear infection - n/a - [n/a - n/a - n/a]), [HYDROCORTISONE ACETATE, POLYMYXIN B SULFATE, OXYTETRACYCLINE] (C - Ear infection - n/a - [n/a - n/a - n/a]), [KETOCONAZOLE, KETOCONAZOLE PH. EUR.] (C - Dandruff - n/a - [n/a - n/a - Cutaneous]), [NAPROXEN] (C - Pain - n/a - [n/a - n/a - Oral]), [TETRACYCLINE	ICSR
EU-EC- 10009700453	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	HYDROCHLORIDE] (C - Rosacea - n/a - [n/a - n/a - Oral]) Not reported	ICSR
											applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009700454	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009700456	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700459	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700464	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009700468	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Noninfective conjunctivitis (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700469	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthritis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700471	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (7d - Recovered/Resolved -), Pain (7d - Recovered/Resolved -), Photophobia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009700480	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

											Unknown - [n/a - 1{DF} - n/a])		
EU-EC- 10009700481	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	[NORETHISTERONE] (C - n/a - n/a - [n/a - n/a - Oral])	ICS
										Headache (n/a - Recovering/Resolving -),			
										Restlessness (n/a - Recovering/Resolving -)			
:U-EC- 0009700936	16/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
										Pyrexia (2d - Recovered/Resolved -)	applicable - [1d - .3mL - Intramuscular])		
U-EC- .0009701594	16/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Chills (n/a - Recovered/Resolved -),			
										Fatigue (n/a - Recovered/Resolved -),			
										Headache (2d - Recovered/Resolved -),			
										Hot flush (n/a - Recovered/Resolved -)			
:U-EC- .0009690162	15/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Injection site erythema (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site swelling (n/a - Not Recovered/Not Resolved -),			
										Injection site warmth (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pain in extremity (n/a - Not Recovered/Not Resolved -),			
										Peripheral swelling (n/a - Not Recovered/Not Resolved -)			
U-EC- .0009690207	15/08/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Ma l e	No	Syncope (10min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
			Professional	Area						-)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[LEVOCABASTINE, LEVOCABASTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009690448	15/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a -			

	Z.40							. IXuIII	LIIIE L	isting Report			
										Recovering/Resolving -), Nausea (n/a - Not Recovered/Not			
										Resolved -), Oropharyngeal pain (n/a - Recovering/Resolving -),			
										Presyncope (n/a - Not Recovered/Not Resolved -),			
										Vision blurred (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009690500	15/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009690506	15/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009686687	14/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009686745	14/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009686891	14/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Arthralgia (n/a - Not Recovered/Not Resolved -),	immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Musculoskeletal pain (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -),			
										Vertigo (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009686950	14/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pain in extremity (n/a - Recovering/Resolving	applicable - [n/a - 1{DF} -		
										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10009687176	14/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10009687833	14/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Mood swings (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- 10009689287	14/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (3d - Recovered/Resolved -), Body temperature increased (n/a - Recovering/Resolving -), Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovering/Resolving -),			

0.11.2022 1	2.40							. IXuII	LINE L	isting Report			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (12h - Recovered/Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Palpitations (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009689292	14/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
										Chills (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Injection site inflammation (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site swelling (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009689529	14/08/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009672086	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Sinus tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1{DF} -	Not reported	<u>ICSR</u>
EU-EC- 10009673863	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovering/Resolving -),	COVID-19	Not reported	ICSR
										Rash (n/a - Recovering/Resolving -)	immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009674392	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -),	immunisation - n/a -	Not reported	<u>ICSR</u>
										Vaccination site pain (n/a - Recovering/Resolving -)	[n/a - n/a - n/a])		
EU-EC- 10009674805	13/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diabetic ketoacidosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	- n/a])		
										Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC-	13/08/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Blood glucose	TOZINAMERAN	HUMALOG [INSULIN LISPRO]	ICSR

30.11.2022 1	2.48							Run	Line L	isting Report			
10009675838			Professional	European Economic Area	available	Years	Specified			increased (2d - Recovered/Resolved - Other Medically Important Condition), Condition aggravated (2d - Recovered/Resolved - Other Medically Important Condition), Diabetes mellitus	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 150ug - n/a])	
										(n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Recovered/Resolved -)			
EU-EC- 10009676418	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009676622	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (1d - Recovered/Resolved -),			
EU-EC-	13/08/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Headache (1d - Recovered/Resolved -) Hyperhidrosis (n/a -	TOZINAMERAN	Not reported	ICSR
10009676864	,,		Healthcare Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Seizure (45s - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (45s - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009676986	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pericardial effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009677208	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Joint swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Unknown - Caused/Prolonged Hospitalisation), Synovial cyst (n/a -	.,,,,,		
										Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009677241	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain lower (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
				Aicd						Appendicitis (289h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	applicable - [n/a - n/a - Intramuscular])		
	1	1	1	T	T	1	T	1		Τ	1	T T	

0.11.2022 1	21.0							· (aii		isting Report			
EU-EC- 10009677700	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Recovering/Resolving -), Malaise (1d - Recovered/Resolved -), Muscular weakness (1d - Muscular weakness (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10009677725	13/08/2021	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- 10009678291	13/08/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						-), Fatigue (1d - Recovered/Resolved -),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (1d - Recovered/Resolved -),			
										Myalgia (1d - Recovered/Resolved -), Oropharyngeal pain			
										(n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009678333	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Painful respiration (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- 10009678820	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tonsillitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009678850	13/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (47d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ACRIVASTINE, DIPHENHYDRAMINE HYDROCHLORIDE, DIPHENHYDRAMINE HYDROCHLORIDE, ZINC ACETATE] (C - Croup infectious - n/a - [n/a - n/a - Oral]),	ICSR
												[PREDNISOLONE] (C - Croup infectious - n/a - [n/a - n/a - Oral])	
EU-EC- 10009679147	13/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 Immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Lymph node pain (n/a - Unknown - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tenderness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009679463	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

٠.	J.11.2022 1										isting report			
	EU-EC- 10009679757	13/08/2021	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), Condition aggravated (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
											Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a			
											- Not Recovered/Not Resolved - Other Medically Important Condition),			
											Neuropathy peripheral (n/a - Unknown - Other Medically Important Condition),			
											Pain (n/a - Unknown - Other Medically Important Condition),			
											Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
											Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10009679791	13/08/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Recovered/Resolved - Life Threatening), Cyanosis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	<u>ICSR</u>
											Recovered/Resolved - Life Threatening), Dyspnoea (n/a - Recovered/Resolved	- İntramuscular])		
											- Life Threatening), Heart rate increased (n/a -			
											Recovered/Resolved - Life Threatening), Local reaction (n/a - Recovered/Resolved			
											-), Oxygen saturation decreased (n/a - Recovered/Resolved - Life Threatening),			
											Rhonchi (n/a - Recovered/Resolved - Life Threatening)			
	EU-EC- 10009681076	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											Lymphadenopathy (n/a - Recovered/Resolved -)			
	EU-EC- 10009681353	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaphylactic reaction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
											Dyspnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
	EILEC	13/00/202	Contract	Non	Europe	Not	12.47	Adoles	Mole	Me	Nausea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIDNATY	Not specified.	ICC
	EU-EC- 10009681999	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	ıvidl€	No	- Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>

1.11.2022 1	2.40							IXuII	LIIIE L	isting Report			
EU-EC- 10009682037	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ischaemic stroke (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]), [ETHINYLESTRADIOL, LEVONORGESTREL, PLACEBO] (S - Hormonal contraception - n/a - [n/a - 1{DF} - n/a]	Not reported	ICSI
EU-EC- 10009682059	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - Intramuscular])	Not reported	ICSI
EU-EC- 10009682099	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (6d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10009682179	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSI
EU-EC- 10009682189	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10009682199		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cellulitis (n/a - Recovering/Resolving - Other Medically Important Condition), Chills (n/a - Recovering/Resolving -), Enythema (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Groin pain (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -), Muscle swelling (n/a - Recovering/Resolving -), Muscle swelling (n/a - Recovering/Resolving -), Musculoskeletal stiffness (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Withe blood cell cont increased (n/a - Recovering/Resolving -), White blood cell count increased (n/a - Recovering/Resolving -), White blood cell count increased (n/a - Recovering/Resolving -),		Not reported	

1.11.2022 1		I	ı	I	ı	ı	ı	ı	LII10 L	ISting Report	I	I	1
										Recovering/Resolving -)			
EU-EC- 10009682214	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009682226	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009682234	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009682248	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009682274	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Ma l e	No	Axillary pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009682275	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anxiety (n/a - Recovering/Resolving -), Decreased appetite (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009682278	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009682279	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Muscle fatigue (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Vaccination site erythema (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009682283	13/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009682308	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Resolved -) Rash (6d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009682311	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysgeusia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009682331	13/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009682336	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Influenza like illness (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009682342	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

									applicable - [1d - .3mL -		
									Intramuscular])		
1 Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (2d - Recovered/Resolved -), Chest pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3ml -	Not reported	ICS
								-), Dizziness (n/a - Recovering/Resolving	Intramuscular])		
								Influenza like illness (n/a - Not Recovered/Not Resolved -),			
								Malaise (2d - Recovered/Resolved			
1 Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Pyrexia (7d - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICS
1 Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angioedema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICS
1 Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICS
1 Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (n/a - Recovered/Resolved -), Insomnia (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICS
1 6		F	Nist	12.17	A d - 1	F	NI.	-)	COMMENSATO	Niek were eine d	100
1 Spontaneous			available	Years	Adolescent	remale	No	(4d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICS
1 Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (2d - Recovered/Resolved -), Nausea (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
								Recovered/Resolved	1{DF} -		
1 Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
								-),	applicable - [n/a -		
								Recovering/Resolving -),			
								Injection site erythema (n/a - Recovering/Resolving -),			
								Injection site inflammation (n/a - Recovering/Resolving -).			
								Injection site pruritus (n/a - Recovering/Resolving			
								Injection site warmth (n/a - Recovering/Resolving			
								Malaise (n/a - Not Recovered/Not Resolved -),			
								Myalgia (n/a - Recovering/Resolving -),			
2	21 Spontaneous 21 Spontaneous 21 Spontaneous 21 Spontaneous 21 Spontaneous	Professional	Professional Area Professional European Economic Area Spontaneous Healthcare Professional Economic Area Spontaneous Non Healthcare Professional Economic Area Non Healthcare Professional Economic Area Spontaneous Non European Economic Area Spontaneous Healthcare Professional Economic Area Spontaneous Non European Economic Area Spontaneous Non European Economic Area Spontaneous Non Healthcare Professional Economic Area	Professional Area Professional European Professional Economic Area Spontaneous Healthcare Professional Economic Area Not available Area Spontaneous Non Healthcare Professional Economic Area Spontaneous Non Healthcare Professional European Area Spontaneous Non Healthcare Professional Area Spontaneous Non Healthcare Professional European Area Spontaneous Healthcare Professional European Area Spontaneous Non Healthcare Economic Area	Professional Area Professional Area Professional European Available Professional Economic Area Professional European Professional Economic Professional Economic Area Professional European Professional Economic Professional Professional Economic Professional Economic Professional Profes	Professional Area European Professional Economic Area Professional Economic Area Professional Economic Area Not available 12-17 Adolescent Years Adolescent Years Adolescent Years Adolescent Years Adolescent Years Professional Economic Area Professional Economic Area Not available 12-17 Years Adolescent Years Adolescent Years Adolescent Years Professional Economic Area Professional Professional Economic Area	Professional Area Professional Profession	Professional Area Professional Area European Professional European Not Area Professional Area Not Adolescent Male No Professional European Not Area Professional Area Professional Area Not Not Non Healthcare Professional Area Professional Area Professional Area Not	Professional Area Professional Area Professional Area Profes	Professional Area Prof	Professional Area Area Professional Professi

										Recovering/Resolving			
:U-EC- .0009684020	13/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	IC
										Attention deficit hyperactivity disorder (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition),			
										Chills (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),			
										Fatigue (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),			
										Influenza (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),			
										Myalgia (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Life Threatening, Disabling, Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition)			
J-EC- 0009684227	13/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Areflexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[LISDEXAMFETAMINE DIMESYLATE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 30mg - Oral])	
										infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Chills (2d - Recovered/Resolved -), Diarrhoea (6d -			
										Recovered/Resolved -), Diarrhoea			
										haemorrhagic (n/a - Unknown - Other Medically Important Condition),			
										Guillain-Barre syndrome (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (6d - Recovered/Resolved -),			
										Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
U-EC-	13/08/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Dry mouth (10min -	COMIRNATY	Not reported	†

30.11.2022 1	2.40							IXuII	LIIIe L	Isting Report			
10009684290			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (2d - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Syncope (10min - Recovered/Resolved			
EU-EC- 10009684368	13/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nasopharyngitis (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- 10009684529	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Defaecation urgency (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009684675	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Rash erythematous (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009684877	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Muscle contractions involuntary (n/a - Recovering/Resolving -), Myoclonus (n/a - Recovering/Resolving	immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009684878	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Burning sensation (n/a - Recovering/Resolving -), Chest discomfort (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Recovering/Resolving -)	immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009684895	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site swelling (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	[FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009684907	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Palpitations (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -), Tonsillar hypertrophy (n/a - Not Recovered/Not Resolved -)	1{OF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009684917	13/08/2021	Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Adolescent		No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009684918	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	C-reactive protein increased (n/a - Recovering/Resolving -), Limb discomfort (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	immunisation - Dose not changed - [n/a - 1{DF} - n/a])	EMADINE [EMEDASTINE, EMEDASTINE DIFUMARATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]), [AZELASTINE HYDROCHLORIDE, FLUTICASONE PROPIONATE] (C - Seasonal allergy - n/a - [n/a - n/a - Nasal]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]), [FEXOFENADINE HYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a -	

Processed Composition Processed).11.2022 1	2.48							Run	Line	Listing Report			
March Marc													[MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a -	
Proceedings Processor Pr	EU-EC- 10009684933	13/08/2021	Spontaneous		Economic			Adolescent	Female	No	Recovering/Resolving - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -		ICS
Perfection Per											(n/a - Recovering/Resolving - Caused/Prolonged			
Electrons 1,3116/2012 Sportaneous Non-Professor Recommerce	EU-EC- 10009684973	13/08/2021	Spontaneous		Economic			Adolescent	Female	No	Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]), [FLUCONAZOLE] (C - Vulvovaginal candidiasis - n/a -	
ELE-CI 10/96/09/20 Sportaneous from enable contents of the feather of whotestoral from enable contents of the feather of the feath	EU-EC- 10009684974	13/08/2021	Spontaneous	Healthcare	Economic			Adolescent	Female	No	- Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -		ICS
Healthcare Communic Professional Area Professional Profes	EU-EC- 10009685294	13/08/2021	Spontaneous	Healthcare	Economic			Adolescent	Female	No	Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a	Not reported	ICS
EU-EC 12/08/2021 Spontaneous Healthcare European Area More Professional Committee European Not Professional Committee C	EU-EC- 10009685384	13/08/2021	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
Professional Economic available Years Specified Recovered/loc Recovered/loc Recovered/Resolved - Other Medically Important COVID-19 Immunication - Not composed the Recovered Resolved - Other Recovered Resolved	EU-EC- 10009658974	12/08/2021	Spontaneous		Economic				Female	No	Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICS
EU-EC- 1009660851 12/08/2021 Spontaneous Professional Pr	EU-EC- 10009660836	12/08/2021	Spontaneous		Economic				Female	No	Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL -	Not reported	ICS
EU-EC- 1009566976 EU-EC- 10095661108 EU-EC- 10095661108 EU-EC- 10095661108 EU-EC- 1009566976 EU-EC- 1009566976 EU-EC- 12/08/2021 Spontaneous Room Room Room Room Room Room Room Room	EU-EC- 10009660851	12/08/2021	Spontaneous		Economic				Male	No	Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperhidrosis (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a 3mL -	Not reported	ICS
EU-EC- 10009660976 EU-EC- 10009600976 EU-EC- 10009660976 EU-EC- 1000960976 EU-EC- 10009660976 EU-EC- 1000960976 EU-EC- 10009760976 EU-EC- 10009760											Hospitalisation), Syncope (1d - Recovered/Resolved - Caused/Prolonged			
Healthcare Professional Area Specified											Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009661108 EU-EC- 10009661108 EU-EC- 1000966108 EU-EC- 1000	10009660976	12/08/2021	Spontaneous	Healthcare	Economic				remaie	INO	Recovered/Resolved -), Headache (1d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICS
EU-EC- 10009661108 European Economic Area Not Specified Female Specified Femal											Increased appetite (1d - Recovered/Resolved -),			
EU-EC- 10009661108											Recovered/Resolved -), Vaccination site pain (1d -			
-) "	EU-EC- 10009661108	12/08/2021	Spontaneous		Economic				Female	No	-) Ecchymosis (6d - Recovered/Resolved -), Petechiae (6d -	[TOZINAMERAN] (S - COVID-19 prophylaxis - Drug withdrawn - [n/a3mL -	Not reported	ICS
	ELLEC	12/09/2021	Cnontangous	Ugaltheara	Europoon	Not	12.17	Adologoopt	Fomale	No	-)	-	Not reported	ICSF

J.11.2022 I	Z.40							Kull	LIIIE L	isting Report			,
10009662387			Professional	Economic Area	available	Years				Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009662459	12/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Blood pressure decreased (0d - Recovered/Resolved -),			
										Pallor (0d - Recovered/Resolved -),			
										Vomiting (0d - Recovered/Resolved -)			
EU-EC- 10009662901	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Malaise (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009663478	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema nodosum (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (n/a - Unknown -),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009663817	12/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye disorder (0d - Recovered/Resolved - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSF
										Fall (0d - Recovered/Resolved - Disabling, Other Medically Important Condition),	- n/a])		
										Loss of consciousness (0d - Recovered/Resolved - Disabling, Other Medically Important Condition),			
										Malaise (0d - Recovered/Resolved - Disabling),			
										Myalgia (0d - Recovered/Resolved - Disabling),			
										Nausea (0d - Recovered/Resolved - Disabling),			
										Pain in extremity (0d - Recovered/Resolved - Disabling, Other Medically Important Condition),			
										Pallor (0d - Recovered/Resolved - Disabling, Other Medically Important Condition),			
										Vomiting (0d - Recovered/Resolved - Disabling, Other Medically Important Condition)			
EU-EC- 10009663890	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU EC	12/00/202	Cnort-	Non	Fuga	Net	12.17	Ada	Mo!-	No	Recovered/Not Resolved -)		Not reported	100-
EU-EC- 10009663912	12/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Ma l e	No	Dermatitis allergic (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Lip swelling (n/a -			

1.11.2022 1	Z. 10	I	ı	ı	ı		ı	ı (uii	 	Isling Report	1	I	
										Recovered/Resolved -)			
EU-EC- 10009664408	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
										Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not	1{DF} - n/a])		
EU-EC-	12/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Fomalo	No	Resolved -) Cellulitis (n/a - Not	COMIRNATY	Not reported	ICSF
10009664868	12/06/2021	Spontaneous	Healthcare Professional	Economic	available	Years	Adolescent	remaje	NO	Recovered/Not Resolved -), Dyspnoea (13d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved -), Headache (13d - Recovered/Resolved			
										Pyrexia (2d - Recovered/Resolved			
EU-EC- 10009664870	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site hypoaesthesia (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Paraesthesia (2d - Recovered/Resolved -)			
EU-EC- 10009665082	12/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009665106	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009665281	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Nausea (2d - Recovered/Resolved -),	[n/a - 2{DF} - n/a])		
										Non-cardiac chest pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (2d - Recovered/Resolved -),			
										Vomiting (2d - Recovered/Resolved -)			
EU-EC- 10009665495	12/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Unknown -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Unknown -), Pain in extremity (n/a -	[.,,a _[a, j .,,a])		
										Recovered/Resolved -),			
FIL FO	12/00/2021	Constant	NI		NI-4	12.17	A dele	NA-1-	NI.	Vomiting (n/a - Unknown -)	COMMENTATIV	Natural	TCCD
EU-EC- 10009665508	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Vasculitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10009665834	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a 3mL - n/a])	Not reported	ICSR
										Fatigue (0d - Recovered/Resolved -),			
										Headache (0d - Recovered/Resolved -)			
EU-EC- 10009666669		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009666909	12/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Condition), Dizziness (n/a -	- n/a])		

0.11.2022 1	2.48							Run	Lille L	isting Report			
										Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
EU-EC-	12/08/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition) Chills (0d -	COMIRNATY	Not reported	ICSR
10009667190	,,		Healthcare Professional	Economic	available	Years	Specified			Recovering/Resolving - Disabling),			
										Malaise (0d - Recovering/Resolving - Disabling),	applicable - [n/a - n/a		
										Myalgia (0d - Recovering/Resolving - Disabling),			
										Pyrexia (0d - Recovering/Resolving - Disabling),			
										Seizure (0d - Recovering/Resolving - Disabling)			
EU-EC- 10009667505	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009668271	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
										Erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Pruritus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009668396	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epididymitis (n/a - Recovering/Resolving - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009668399	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009668409	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (1d - Recovered/Resolved - Other Medically Important	Subcutaneous]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Condition), Malaise (1d - Recovered/Resolved - Other Medically	1{DF} - Intramuscular])		
EU-EC- 10009668456	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Spontaneous haematoma (n/a - Recovering/Resolving - Other Medically Important Condition)	immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009668484	12/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypotension (1d - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Tachycardia (1d - Recovered/Resolved -),	iga iya iya])		
										Vomiting (0d -			

.11.2022 1	2 . 40	I	I	I	ı	ı	ı	Kuii	LII 16 L	Isling Report	ı	I	1
										Recovered/Resolved			
J-EC- 0009668599	12/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Ocular hyperaemia (n/a - Not Recovered/Not Resolved -)	applicable - [1d - 1{DF} - Intramuscular])		
U-EC- 0009668696	12/08/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
0003000030			Professional		available	rears				Recovering/Resolving	COVID-19 immunisation - Not applicable - [32d - 1{DF} - Intramuscular])		
U-EC- 0009668710	12/08/2021	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Adolescent	Male	No	Testicular pain (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSI
0009668710			Professional	Area	avallable	rears				Resolved -)	COVID-19 immunisation - Not applicable - [1d - .3mL -		
	12/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Lymphadenopathy	Intramuscular]) COMIRNATY	Not reported	ICS
0009668711			Professional	Area	available	Years				(n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -		
	12/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Lymphadenitis (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSI
.0009668723			Healthcare Professional	Economic Area	available	Years				-), Menstrual disorder	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -		
										(n/a - Not Recovered/Not	[Intramuscular])		
EU-EC- 10009668725	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Purpura (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
	10/00/0001										applicable - [n/a - n/a - Intramuscular])		
:U-EC- .0009668728	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (45d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	<u>ICSF</u>
										Dyspnoea (45d - Not Recovered/Not Resolved -)	[n/a - 1{DF} - Intramuscular])		
EU-EC- .0009668772	12/08/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
			Professional	Area						Injection site pain (n/a - Recovering/Resolving	Immunisation - n/a - [n/a - n/a - n/a])		
										-), Nausea (n/a - Recovering/Resolving			
										-),			
										Painful respiration (n/a - Recovering/Resolving -),			
										Pyrexia (2d - Recovered/Resolved -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10009668846	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	ICSF
										Headache (n/a - Recovering/Resolving -),	withdrawn - [1d -		
										Malaise (n/a - Recovering/Resolving -)			
EU-EC- 10009668852	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
											immunisation - Drug withdrawn - [1d - .3mL -		
EU-EC- 10009668855	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (21d - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
										Asthenia (21d - Not Recovered/Not Resolved -)	immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])		
EU-EC- 10009669006	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Headache (1d - Recovered/Resolved - Disabling),	applicable - [n/a - n/a - n/a])		

								, ixuii i	_IIIC L	isting report	1	ı	
										Nausea (1d - Recovered/Resolved - Disabling),			
										Pyrexia (1d - Recovered/Resolved - Disabling)			
EU-EC- 10009669324	12/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	COVID-19 MRNA VACCINE (NUCLEOSIDE	[ATOMOXETINE] (C - n/a - Unknown - [n/a - 80mg - n/a])	<u>ICSR</u>
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),	MODIFIED) COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION		
										Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])		
EU-EC- 10009669929	12/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	[TRANEXAMIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
EU EO	12/00/2021		Non	Area	N	12.17	Non			Pharyngeal swelling (n/a - Unknown -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	TOAD A SETTIMOLI (C / /	TOOD
EU-EC- 10009669952	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Headache (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Injection site inflammation (n/a - Not Recovered/Not Resolved -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site pruritus (n/a - Not Recovered/Not Resolved -),			
										Injection site swelling (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 -),			
										Pain (n/a - Not Recovered/Not Resolved -),			
										Presyncope (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009669960	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	White blood cell count increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
											immunisation - Not applicable - [1d - n/a - n/a])	[LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009670975	12/08/2021	Spontaneous	Healthcare	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Bradycardia (n/a - Recovering/Resolving - Life Threatening,	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009671097	12/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Erythema (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						- Caused/Prolonged Hospitalisation),	COVID-19 immunisation - Not applicable - [n/a -		
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	1{DF} - n/a])		
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Peripheral swelling			
1											•		1

30.11.2022 1	12.48							Run	Line i	_isting Report			
										(n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Skin discolouration			
										(n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation)			
EU-EC- 10009671113	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009671709	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site reaction (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Resolved -), Tremor (n/a - Not Recovered/Not Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-	12/08/2021	Spontaneous		Non	Not	12-17	Not	Male	No	Pneumothorax (n/a -	TOZINAMERAN	Not reported	ICSR
10009672186			Healthcare Professional	European Economic Area	available	Years	Specified			Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009672393	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
											applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009672583	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
											applicable - [1d - n/a - n/a])		
EU-EC- 10009672739	12/08/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Contusion (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	<u>ICSR</u>
										Headache (2d - Recovered/Resolved -),	withdrawn - [1d - n/a - Intramuscular])		
										Syncope (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009673227	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Unknown -),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009673233	12/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling cold (n/a - Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity			
										(n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10009646765	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			roressionar	/ wed						Nausea (n/a - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009648331	11/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10005070331			. TOTCSSIUIIdI	Area	avanable	icais	openieu			Resolved -)	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC- 10009648334	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
EU-EC-	11/08/2024	Spontaneous	Non	European	Not	12-17	Not	Ma i e	No	Injection site pain	- Intramuscular])	Not reported	ICSR
10009648665	11,00,2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	i-ialC	140	(n/a - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	The reported	ICSK
EU-EC-	11/08/2021	Spontaneous		European	Not	12-17	Not	Female	No	Asymptomatic	- Intramuscular]) COMIRNATY	Not reported	ICSR
10009648909			Healthcare Professional	Economic Area	available	Years	Specified			COVID-19 (n/a - Unknown - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not		

0.11.2022 1	2.48							Run	Line L	isting Report			
										Condition),	applicable - [n/a - n/a - n/a])		
										Drug ineffective (n/a - Unknown - Other Medically Important	, 2,		
										Condition)			
EU-EC- 10009650452	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (12h - Recovered/Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION	Not reported	ICSR
										Fatigue (24h - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Pain in extremity (2d	- Intramuscular J)		
										Recovered/Resolved			
EU-EC- 10009650503	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (24h - Recovered/Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S -	Not reported	ICSR
										Fatigue (24h - Recovered/Resolved -),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Pain in extremity (48h - Recovered/Resolved -)			
EU-EC- 10009650519	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medicinal Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
										Condition), Vaccination site		[TOPIRAMATE] (C - Epilepsy - n/a - [n/a - n/a - n/a])	
										erythema (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC-	11/08/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Condition) Rash (n/a - Not	TOZINAMERAN	Not reported	ICSR
10009650693		·	Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	·	
										Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	. 3		
EU-EC- 10009650829	11/08/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S -	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a	ICSR
10009030029			TOICSSIONA	Economic Area	avaijabje	Icars	эрестеч			- Other Medically Important Condition),	COVID-19 immunisation - Not	- n/a - [n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a -	
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	- Intramuscular])	n/a - [n/a - n/a - n/a], [MUPIROCIN] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009651645	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Nausea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Vomiting (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Unknown - [n/a - .3mL - Intramuscular])		
EU-EC- 10009651792	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	 	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009651850	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Petechiae (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Purpura (n/a - Recovering/Resolving -)	applicable - [n/a -		
EU-EC- 10009653206	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Cough (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
											(-, '', MJ)		

2.48							Run	Line L	Isting Report			
									Malaise (n/a - Not Recovered/Not Resolved -),			
									Myalgia (n/a - Recovering/Resolving			
									Nasopharyngitis (n/a - Not Recovered/Not			
									Pyrexia (n/a - Not Recovered/Not			
11/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
									Circulatory collapse (n/a - Recovered/Resolved - Other Medically Important Condition),			
									Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)			
11/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -),	COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										applicable - [n/a -	[TACROLIMUS] (C - n/a - n/a - [n/a - n/a - n/a]),	
									Headache (n/a - Not Recovered/Not Resolved -),		[DESOXIMETASONE] (C - n/a - n/a - [n/a - n/a - n/a])	
									Myalgia (n/a - Recovering/Resolving -),			
									Pyrexia (n/a - Not Recovered/Not			
11/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adult	Male	No	Presyncope (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
11/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Male	No	Chills (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
									Fatigue (n/a -	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
									Headache (n/a - Recovering/Resolving -),			
									Malaise (n/a - Recovering/Resolving -),			
									Myalgia (n/a - Recovering/Resolving -),			
									Nausea (n/a - Recovering/Resolving -),			
									Syncope (0d - Recovered/Resolved			
11/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
			Area						Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - n/a])		
11/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
11/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Haematochezia (n/a	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
11/00/2021	Spontaneous	Professional		Not	12-17	Not	Male	No	Recovered/Resolved - Caused/Prolonged Hospitalisation) Axillary pain (n/a -	Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY	Not reported	ICSR
	11/08/2021 11/08/2021 11/08/2021 11/08/2021	11/08/2021 Spontaneous 11/08/2021 Spontaneous 11/08/2021 Spontaneous 11/08/2021 Spontaneous 11/08/2021 Spontaneous	11/08/2021 Spontaneous Non Healthcare Professional 11/08/2021 Spontaneous Non Healthcare Professional Area 11/08/2021 Spontaneous Non Healthcare Professional Realthcare Professional I1/08/2021 Spontaneous Non Healthcare Professional Realthcare Professional I1/08/2021 Spontaneous Non Healthcare Professional Reconomic Area Not Economic Professional I1/08/2021 Spontaneous Non Healthcare Professional Reconomic Area Not European Not Area Non Healthcare Professional Reconomic Area Not European Not Area Non Healthcare Professional Reconomic Area Not European Not European Not European Not European Not European Not Area Non Healthcare Professional Reconomic Area Not European Not European Not European Not European Not European Not European Not Not Not European Not Not European Not	11/08/2021 Spontaneous Non Healthcare Professional Realthcare Reconomic Realthcare Professional Realthcare Professional Realthcare Reconomic Realthcare Professional Realthcare Reconomic Realthcare Professional Realthcare Reconomic Realthcare Realthcare Reconomic Realthcare Reconomic Realthcare Realthcare Realthcare Realthcare Re	11/08/2021 Spontaneous Non Healthcare Professional Area Not European Area Not European Professional Area Not European Not European Not European Not Not Not Specified Not Not Not Not Not European Area Not European Area Not Not Not Specified Not Not Not Not Not Not Specified Area Not Not 12-17 Not Specified Not	11/08/2021 Spontaneous Non Healthcare Professional 11/08/2021 Spontaneous Non European Not I2-17 Not Specified Permale I1/08/2021 Spontaneous Non European Not I2-17 Not Specified Permale I1/08/2021 Spontaneous Non European Not I2-17 Not Specified Permale I1/08/2021 Spontaneous Non European Not I2-17 Not Specified Permale I1/08/2021 Spontaneous Non European Not I2-17 Not Specified Permale I1/08/2021 Spontaneous Non European Not I2-17 Not Specified Male	11/08/2021 Spontaneous Non-Healthcare Professional Professional Area Libropean Area Lib	Participation Participatio	11/08/2021 Sportdenesus Non	1.766-2021 Sourcamean Professor Color Pr		

										Recovered/Not	applicable - [n/a -	1	
EU-EC-	11/09/2021	Chontanoous	Hoaltheara	European	Not	12-17	Adolescent	Malo	No	Resolved -)	1{DF} - n/a]) COMIRNATY	Not reported	ICSR
10009656158	11/06/2021	Spontaneous	Professional	Economic	available	Years	Adojescent	Маје	INO	Lymphadenitis (n/a - Not Recovered/Not	[TOZINAMERAN] (S -	Not reported	ICSK
				Area						Resolved - Other Medically Important	COVID-19 immunisation - Not		
										Condition),	applicable - [1d -		
										Lymphadenopathy	.3mL - [Intramuscular])		
										(n/a - Not Recovered/Not			
										Resolved - Other			
										Medically Important Condition)			
EU-EC-	11/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Dizziness (n/a -	COMIRNATY	Not reported	ICSR
10009656173			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved	[TOZINAMERAN] (S - COVID-19		
											immunisation - Not		
										Pyrexia (n/a - Recovering/Resolving	applicable - [n/a - 1{DF} -		
										-),	Intramuscular])		
										Syncope (n/a			
										Recovered/Resolved - Other Medically			
										Important Condition),			
										Vision blurred (n/a - Recovered/Resolved			
EIL EC	44 (00 (2024	6			N1-1	12.17		N4 - 1 -		-)	COMPRIATO	Notes	TOOD
EU-EC- 10009656180	11/08/2021	Spontaneous	Professional	European Economic	Not available	12-17 Years	Adolescent	маю	No	Myocarditis (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						- Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not		
										nospitalisationy	applicable - [n/a -		
											1{DF} - Intramuscular])		
EU-EC-	11/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Pericarditis (n/a -	COMIRNATY	Not reported	ICSR
10009656211			Professional	Economic Area	available	Years				Not Recovered/Not Resolved - Other	[TOZINAMERAN] (S - COVID-19		
										Medically Important Condition)	immunisation - Not applicable - [1d -		
										Conditions	1{DF} -		
EU-EC-	11/08/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Cellulitis (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
10009656269	,,		Professional	Economic	available	Years				Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S -		1
				Area						Hospitalisation),	COVID-19 immunisation - n/a -		
										Headache (4d -	[1d - 1{DF} - Intramuscular])		
										Recovered/Resolved	Indumuscular jy		
										- Caused/Prolonged Hospitalisation),			
										Lymphadenopathy			
										(n/a -			
										Recovering/Resolving - Caused/Prolonged			
										Hospitalisation),			
										Pyrexia (4d -			
										Recovered/Resolved - Caused/Prolonged			
										Hospitalisation),			
										Rash pustular (n/a -			
										Recovering/Resolving - Caused/Prolonged			
										Hospitalisation)			
EU-EC- 10009656372	11/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
			Professional	Area						Recovered/Not Resolved -)	COVID-19 immunisation - Not		
										Resolved -)	applicable - [n/a -		
											1{DF} - Intramuscular])		
EU-EC-	11/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Lip oedema (24h -	COMIRNATY	Not reported	ICSR
10009656395			Professional	Economic Area	available	Years				Recovered/Resolved	[TOZINAMERAN] (S - COVID-19		
										Tongue oedema (24h	immunisation - Not		
										- '	1{DF} -		
										Recovered/Resolved	Intramuscular])		
EU-EC-	11/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	Herpes zoster (n/a	COMIRNATY	Not reported	ICSR
10009656396			Professional	Economic Area	available	Years				Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19		
											immunisation - Not applicable - [1d -		
											1{DF} -		
EU-EC-	11/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Flushing (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
10009656538	11,00,2021	оронивновая	Healthcare	Economic	available	Years	radiescent	, idic		Recovered/Resolved	[TOZINAMERAN] (S -	The reported	1001
			Professional	Area						-)	COVID-19 immunisation - Not		
											applicable - [n/a - 1{DF} -		
											Intramuscular])		
EU-EC- 10009656556	11/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adult	Female	No	Angioedema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	<u>ICSR</u>
100000000000000000000000000000000000000			Professional		a validate	, curs				Jimaiowii)	COVID-19		
											immunisation - Not applicable - [n/a -		
											1{DF} - Intramuscular])		
EU-EC-	11/08/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Angioedema (5d -	COMIRNATY	Not reported	ICSR
10009656562			Professional	Economic Area	available	Years				Recovered/Resolved	[TOZINAMERAN] (S - COVID-19		_
1	I	I	I	1	I	I	I	I	1	Ι'	1-5 17	I	

											immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009656583	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL -	Not reported	ICSR
EU-EC- 10009656586	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL -	Not reported	ICSR
EU-EC- 10009656860	11/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009657129	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (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- 10009657209	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (3d - Recovering/Resolving -), Heavy menstrual bleeding (3d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009658057	11/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Disabling) Generalised tonic- clonic seizure (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Seizure (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Sinusitis (n/a - Unknown -), Vaccination site pain (n/a - Recovered/Resolved			
EU-EC- 10009658541	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Fatigue (n/a - Recovered/Resolved -), Sleep disorder (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Vaccination site pain (n/a - Recovered/Resolved			
EU-EC- 10009658674	11/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Recovered/Resolved -), Back pain (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [n/a - 150mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - n/a])	ICSR
										Dizziness (n/a - Recovered/Resolved		1/4 [1/4 2511g 1/4])	
										Feeling hot (n/a - Recovered/Resolved -),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Mydriasis (n/a - Recovered/Resolved -),			
										Paraesthesia (n/a - Recovered/Resolved -),			
										Tinnitus (n/a -			

J.11.2022 I	2.70							IXuII	LIIIE L	isting Report			
										Recovered/Resolved			
										Tremor (n/a - Recovered/Resolved -),			
										Visual impairment (n/a - Recovered/Resolved -)			
EU-EC- 10009659284	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pain (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vaccination site swelling (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009659285	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC- 10009659296	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deafness unilateral (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Migraine (0d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009659304	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009659305	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[FLUOCINOLONE ACETONIDE, FLUOCINOLONE ACETONIDE PH. EUR, NEOMYCIN SULFATE, POLYMYXIN B SULFATE, FLUOCINOLONE ACETONIDE, NEOMYCIN, POLYMYXIN B, FLUOCINOLONE ACETONIDE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]), [HYDROCORTISONE] (C - Eczema - n/a - [n/a - n/a - Fl/a - N/a - F	ICSR
												Cutaneous]), [KETOCONAZOLE, KETOCONAZOLE PH. EUR.] (C - Dandruff - n/a - [n/a - n/a - Cutaneous])	
EU-EC- 10009659306	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009659309	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009659310	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Intramuscular])	[TRAMADOL HYDROCHLORIDE] (C - Pain - n/a - [71d - n/a - Oral])	ICSR

0.11.2022 1	2.48							Run	Line L	isting Report			
EU-EC- 10009659438	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain of skin (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Rash (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009659443	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Sensitive skin (2d - Recovered/Resolved -) Influenza (n/a - Not Recovered/Not Resolved -), Otitis media (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
EU-EC- 10009659446	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Fema l e	No	Recovering/Resolving -) Musculoskeletal stiffness (n/a - Recovering/Resolving - Disabling), Myalgia (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	[DESOGESTREL] (C - Oral contraception - n/a - [n/a - 75ug - Oral])	ICSF
EU-EC- 10009659447	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Recovered/Not Resolved - Disabling) Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009659448	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Disabling), Dyspnoea (n/a - Unknown - Disabling), Pain (n/a - Unknown	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Ear infection - n/a - [10d - 800mg - Oral])	ICSF
EU-EC- 10009659451	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{OF} - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSF
EU-EC-	11/08/2021	Spontaneous		European	Not	12-17	Adolescent	Ma i e	No	Myalgia (n/a - Unknown -), Vaccination site pain (n/a - Unknown -) Blood pressure	COMIRNATY	Not reported	ICSF
10009659459			Healthcare Professional	Economic Area	available	Years				decreased (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		
EU-EC- 10009659466	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[CIPROFLOXACIN HYDROCHLORIDE, DEXAMETHASONE, DEXAMETHASONE, CIPROFLOXACIN] (C - Ear infection - n/a - [n/a - n/a - n/a]),	ICSR
										Myalgia (n/a - Recovered/Resolved -)		ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]), IBUPROFEN] (C - Dysmenorrhoea - n/a - [n/a - n/a - Oral]), LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Intra-uterine]), MOMETASONE FUROATE] (C - n/a - n/a - [n/a - n/a -	
EU-EC- 10009659472	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved -), Migraine (14d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Cutaneous]) Not reported	ICSR
EU-EC-	11/00/2021	Spontaneous	Haaltheare	European	Not	12-17	Adolescent	Female	No	Swelling face (4d - Recovered/Resolved -) Dizziness (n/a -	COMIDNATY	[SERTRALINE] (C - Anxiety -	ICCD
LO-EC-	11/08/2021	Spontaneous	nearmcare	European	Not	12-17	Audiescent	remale	INO	Dizziriess (fi/a -	COMIRNATY	[SEKTRALINE] (C - ANXIETY -	ICSR

0.11.2022 1	2.48							Run	Line L	isting Report			
10009659473			Professional	Economic Area	available	Years				Unknown - Caused/Prolonged Hospitalisation), Epistaxis (n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - [n/a - 50mg - n/a])	
										- Caused/Prolonged Hospitalisation),			
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009659474	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Muscle tightness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)	immunisation - Dose not changed - [n/a - 1{DF} - n/a])		
EU-EC- 10009659475	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	1{DF} - n/a])		
EU-EC- 10009659482	11/08/2021	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 - COVID-19 immunisation - Not	Not reported	ICSR
EU EO	11/00/2021		No	-		12.17		N. I.		Pyrexia (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a])		YOSD
EU-EC- 10009659485	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	маю	No	Pyrexia (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Swelling (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009659489	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
EU-EC- 10009659490	11/08/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovering/Resolving	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional							Fatigue (n/a - Recovering/Resolving	COVID-19 immunisation - Not applicable - [n/a -		
										Headache (n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving -),			
										Pain (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10009659494	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Acute kidney injury (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Azotaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (36h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009659500	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

0.11.2022 1	2.40							IXuII	LIIIE L	isting Report			
										Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Limb discomfort (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009659503	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),	applicable - [n/a -		
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vomiting (0d - Recovered/Resolved -)			
EU-EC- 10009659508	11/08/2021	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 - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009659511	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	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 (1d - Recovered/Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009659516	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash erythematous (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- 10009659522	11/08/2021	Spontaneous		١.	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10009659593	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Increased viscosity of upper respiratory secretion (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10009659691	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	1{DF} - Unknown]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009659737	11/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)		Not reported	ICSR
EU-EC- 10009660156	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009660157	11/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved -),	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	10/08/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Syncope (n/a - Not Recovered/Not Resolved -) Erythema (n/a -	COMIRNATY	Not reported	ICCD
LU LC-	10,00,2021	Sportaneous	14011	Luiopeaii	1400	12-17	1100	ciliale	INO	Liyulcilla (II/a -	CONTINUALI	Thou reported	ICSR

	0.11.2022 1	2.48							Run	Line L	isting Report			
	10009635862					available	Years	Specified			Unknown -)	COVID-19 immunisation - n/a - [n/a - n/a -		
2016-00-00-00-00-00-00-00-00-00-00-00-00-00		10/08/2021	Spontaneous		Economic				Female	No	(n/a - Recovered/Resolved -), Pain in extremity (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
10/09/2021 20/09/2021 20/09/2021 20/09/2021 20/09/2022 20/		10/08/2021	Spontaneous		Economic				Male	No	-) Headache (n/a - Recovered/Resolved -), Pyrexia (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
File		10/08/2021	Spontaneous		Economic				Male	No	-) Asthenia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
EU-EC- 100903/2021 Spontaneous Members of European Not 12-17 Net Press Specified Pale No Occasional (Natural Contents) EU-EC- 100903/2021 Spontaneous Heathcare Recorded Professional Avea Not Information (Natural Contents) Avea Not Information (Na											Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not			
											Resolved -)			
EU-EC- 1000635091 I 0/08/2021 Spontaneous Healthcare European Professional Economic Professional Force I 1000635091 EU-EC- 1000635093 I 0/08/2021 Spontaneous Healthcare European Professional Economic Area Not Professional Force I 1000630093 I 0/08/2021 Spontaneous Healthcare European Professional Economic Area I 0/08/2021 Spontaneous Healthcare European Professional Economic European Area I 0/08/2021 Spontaneous Healthcare European Professional Economic European Area I 0/08/2021 Spontaneous Healthcare European Professional Economic European Area I 0/08/2021 Spontaneous Healthcare European Professional Economic European Area I 0/08/2021 Spontaneous Healthcare European Professional Economic European Economic European Europe		10/08/2021	Spontaneous	Healthcare	Economic				Male	No	pain (n/a - Recovering/Resolving -), Chest pain (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	<u>ICSR</u>
	ELLEC	10/09/2021	Sportonoous	Healtheare	European	Not	12.17	Not	Eomala	No	-), Pruritus (n/a - Recovering/Resolving -)	COMIDNATY	Not reported	ICCD
EU-EC- 10009636093 10/08/2021 Spontaneous Healthcare European Not Professional Economic Area Not Professional Area COMIRNATY Not Professional Area COMIRNATY Not Professional Area COMIRNATY Not Professiona		10/06/2021	Sportalieous		Economic				гение	INO	(n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 100963693 10/08/2021 Spontaneous Healthcare Professional Area European Professional Area Not Vears Specified Not Vears Specified Not Professional Specified Not Recovered/Resolved Communication - n/a - Recovered/Resolved - Not reported COVID-19 (namuscular)) Not reported COVID-19 (namuscular) Not reported Covidence Recovering/Resolving - Not Recovering/Resolving - Not Recovering/Resolving - Not Recovering/Resolving - Not Recov											Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a -			
Professional Area Professional Economic Professional	EU-EC-	10/08/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	-)	COMIRNATY	Not reported	ICSR
EU-EC- 1009636571 10/08/2021 Spontaneous Healthcare Professional European Recovering/Resolving Area Healthcare Professional European Recovering/Resolving Area Not reported 12-17 Not reported 2-1009636571 Not periced 2-1009636571 Not periced 2-1009636571 Not periced 2-1009636571 Not reported 2-1009637866 Not		,,			Economic						Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -		
EU-EC- 10/08/2021 Spontaneous Healthcare Professional European Economic Area Non Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Dysphoria (n/a - Recovering/Resolving -), Hyperhidrosis (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resol											Headache (n/a -			
Recovering/Resolving -), Hyperhidrosis (n/a - Recovering/Resolving -), Rash macular (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving -) Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving -) Urticaria cholinergic (n/a - Recovering/Resolving -) Not reported Professional Economic available Professional Female No COVID-19 (n/a - Unknown - Other [TOZINAMERAN] (S -		10/08/2021	Spontaneous		European Economic				Male	No	-) Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
Recovering/Resolving -), Rash macular (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Ourticaria cholinergic (n/a - Recovering/Resolving - Other Medically - Other Medical											Recovering/Resolving			
Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving -) EU-EC- 1009637866 10/08/2021 Spontaneous Healthcare Professional Economic Professional Economic Available Vears Not reported Unknown - Other Unknown - Other [TOZINAMERAN] (S -											Recovering/Resolving -),			
EU-EC- 1009637866 EU-EC- 1009637866 EU-FC- 1009637866 Recovering/Resolving - Other Medically Important Condition), Urticaria cholinergic (n/a - Recovering/Resolving -) COVID-19 (n/a - Unknown - Other [TOZINAMERAN] (S -											Recovering/Resolving -),			
EU-EC- 1009637866											Recovering/Resolving - Other Medically Important			
EU-EC- 10/08/2021 Spontaneous Healthcare 10009637866 Spontaneous Healthcare 1000963786 Spontaneous Healthcare 10009637866 Spontaneous Healthcare 1000963786 Spontaneous Healthcare											(n/a - Recovering/Resolving			
Condition), - n/a]) Vaccination failure		10/08/2021	Spontaneous		Economic			Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICSR

1.11.2022 1	2. 48							Kun	Line L	isting Report	ı	ı	
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10009638132	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	 	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10009638136	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving	[m/a T(b) m/a) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
										- Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10009638219	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Optic nerve disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S -	Not reported	ICS
											Immunisation - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10009638230	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (10d - Not Recovered/Not Resolved -), Nasal congestion (10d - Not Recovered/Not Resolved -), Pyrexia (10d - Not Recovered/Not Resolved -),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICS
										Vomiting (10d - Not Recovered/Not Resolved -)			
EU-EC- 10009638468	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes simplex (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICS
										Pharyngitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
EU-EC- 10009638556	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -), Injection site erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10009638571	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009638626	10/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Myalgia (1d - Recovered/Resolved -),	applicable - [n/a - n/a - Intramuscular])		
										Nausea (1d - Recovered/Resolved -),			
										Pain (1d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -),			
EII EC	10/00/222	Co	New		Nez	12.7=	0.4-1	NA-1		Rash (827min - Recovered/Resolved - Other Medically Important Condition)	COMPRIATE	Not consider	
EU-EC- 10009638718	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR	Not reported	ICSI
										Cough (4d -			1

1.11.2022 1	2.48							Run	Line	_isting Report			
										Recovering/Resolving -), Rhinitis (4d - Recovering/Resolving	applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10009638729	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Heavy menstrual bleeding (n/a - Unknown -), Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ALMOTRIPTAN] (C - n/a - n/a -), [DESOGESTREL] (C - n/a - n/a -), [EBASTINE] (C - n/a - n/a -),	ICS
EU-EC-	10/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Malo	No	Generalised tonic-	COMIRNATY	[PREDNISOLONE] (C - Hypersensitivity - n/a - [5d - n/a - n/a]) Not reported	ICS
10009638883		·	Healthcare Professional	Economic Area	available	Years				clonic seizure (0d - Recovered/Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])		
EU-EC- 10009638986		,		European Economic Area	Not available	12-17 Years	Adolescent		No	Urticaria (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICS
EU-EC- 10009639055	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICS
EU-EC- 10009639174	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Varicella zoster virus infection (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]),	Not reported	ICS
EU-EC-	10/08/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Application site	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) COMIRNATY	Not reported	ICS
10009639578			Healthcare Professional	Economic Area	available	Years				movement impairment (n/a - Unknown -), Application site pain	[TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])		
EU-EC- 10009640508	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a - Unknown -) Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS
EU-EC-	10/08/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Tinnitus (n/a - Not Recovered/Not Resolved -) Cardiovascular	applicable - [n/a - 1{DF} - n/a]) COMIRNATY	Not reported	ICS
10009640765	10,00,2021	Sportaneous	Professional	Economic Area	available	Years	Specified	Tidle		disorder (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Tot reported	
EU-EC-	10/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Formula	No	Unknown - Other Medically Important Condition) Lip swelling (n/a -	COMIRNATY	[FLUTICASONE PROPIONATE]	ICS
10009640831	10/08/2021	Sportaneous	Healthcare Professional	European Economic Area	available	Years	Adolescent	remale	INO	Recovered/Resolved -), Paraesthesia (n/a - Recovered/Resolved	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	(C - n/a - n/a - [n/a - n/a - n/a])	<u>IC.</u>
EU-EC- 10009641466	10/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paresis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10009641601	10/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haematochezia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n	ICS
EU-EC- 10009641635	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Injection site pain (n/a - Not Recovered/Not Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10009642499	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash papular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICS
EU-EC- 10009642869	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a - n/a])	Not reported	IC
511 F2	10/00/2		No	F	late:	10.1				Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPLIA		+-
EU-EC- 10009643167	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Ma l e	No	Anaphylactic shock (n/a - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS

J.11.2022 1	2.40							Kuii		Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009643348	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009643688	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (5d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009643713	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009643949	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (2wk - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009643970	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (8d - Recovered/Resolved -), Premenstrual syndrome (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009644002	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10009644005	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009644425		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure diastolic decreased (n/a - Unknown -), Fall (0d - Recovered/Resolved -), Heart rate decreased (n/a - Unknown -), Presyncope (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - 0ther Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Acne - n/a - [n/a - n/a - Oral])	
EU-EC- 10009645309	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adult	Male	No	Body temperature increased (n/a - Recovering/Resolving -), Chills (1d - Recovered/Resolved -), Myalgia (n/a - Recovering/Resolving -), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009645381	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

J.11.2022 I	2.40							ixuii		isting Report			
										Myalgia (n/a - Recovering/Resolving -),			
										Pain (n/a - Recovering/Resolving -)			
EU-EC- 10009645396	10/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	Not reported	ICSR
										Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition),	- n/a])		
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10009645607	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Migraine (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009646825	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	[DROSPIRENONE, ETHINYLESTRADIOL] (C - Contraception - n/a - [n/a - n/a - Oral]),	<u>ICSR</u>
										Pyrexia (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a])	[IBUPROFEN] (C - Pain - n/a - [n/a - n/a - Oral])	
EU-EC- 10009646827	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved -),	Unknown - [n/a - 1{DF} - n/a])		
										Pain (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10009646828	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
EU-EC- 10009646829	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tenderness (n/a - Not Recovered/Not Resolved -),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Vaccination site pain (3d - Recovered/Resolved -)	Unknown - [n/a - 1{DF} - n/a])		
EU-EC- 10009646830	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009646834	10/08/2021	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 - Dose not changed - [n/a -	Not reported	ICSR
EU-EC- 10009646835	10/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovering/Resolving	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						-), Headache (n/a - Not Recovered/Not Resolved -),	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										Heart rate increased (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009646839	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Breast swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

											Unknown - [n/a -		
EU-EC- 10009646840	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
EU-EC- 10009646843	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Recovering/Resolving -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646848	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10009646849	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Ovarian cyst ruptured (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
EU-EC- 10009646852	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646854	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (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- 10009646855	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646856	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646858	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646859	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646861	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Swelling (n/a - Not Recovered/Not Resolved -), Vaccination site oedema (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	IQUF - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646863	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

30.11.2022 1	2.48					_		Run	Line L	isting Report			
										Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Throat tightness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Tinnitus (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Tremor (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Use of accessory respiratory muscles (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Visual impairment (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10009646864	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (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- 10009646865	10/08/2021	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 - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	ICSR
EU-EC- 10009646874	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Unknown -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	[CHLORAMPHENICOL] (C - Eye infection - n/a - [n/a - n/a - Subconjunctival]), [IBUPROFEN] (C - Pain - n/a - [n/a - n/a - Oral]), [KETOCONAZOLE,	
												KETOCONAZOLE PH, EUR.] (C - Dandruff - n/a - [n/a - n/a - Cutaneous]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypometabolism - n/a - [n/a	
												- n/a - Oral]), [NAPROXEN] (C - Dysmenorrhoea - n/a - [n/a - n/a - Oral]),	
												[PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [PROGUANIL	
												HYDROCHLORIDE, ATOVAQUONE] (C - n/a - n/a - [n/a - n/a - Oral])	
EU-EC- 10009646875	10/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646877	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Headache (2d - Recovered/Resolved -), Myalgia (5d -	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Resolved With Sequelae -), Pyrexia (n/a -			
EU 50	10/00/5	Control	n. te		No.	40.4=	A.1.1	F.		Recovered/Resolved	COMMINIST	FADADALENEZ (G.)	TOOL
EU-EC- 10009646880	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	[ADAPALENE] (C - Acne - n/a - [n/a - n/a - Cutaneous]), [CLOBETASOL PROPIONATE] (C - Eczema - n/a - [n/a - n/a -	ICSR
										Vomiting (n/a - Not Recovered/Not Resolved -)	not changed - [n/a - 1{DF} - n/a])	(C - Eczema - n/a - [n/a - n/a - Cutaneous]), [ETHINYLESTRADIOL,	

0.11.2022 1	2.48									isting Report			
												LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]),	
												[ISOTRETINOIN] (C - Acne - In/a - [n/a - n/a - Oral]),	
												[METRONIDAZOLE, METRONIDAZOLE PH. EUR., METRONIDAZOLE SODIUM] (C - Skin disorder - n/a - [n/a -	
												n/a - Cutaneous]), [MICONAZOLE NITRATE,	
EU-EC-	10/09/2021	Spontaneous	Non	Europoan	Not	12-17	Adolescent	Fomalo	No	Headache (2d -	COMIRNATY	HYDROCORTISONE] (C - n/a - n/a - [n/a - n/a - Cutaneous]) Not reported	ICSR
10009646881	10/08/2021	Spontaneous		European Economic Area	Not available	Years	Adolescent	remale	NO	Recovered/Resolved -), Tongue spasm (2d - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSK
										Visual impairment (2d - Recovered/Resolved			
	10/08/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	-) Myalgia (n/a -	COMIRNATY	OPATANOL [OLOPATADINE,	ICSR
10009646884			Professional	Economic Area	available	Years				Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]),	
											1(81) 1(41)	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]),	I
												[HYDROCORTISONE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]),	
												[LORATADINE] (C - Urticaria - n/a - [n/a - n/a - Oral]),	
												[MOMETASONE FUROATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]),	
												[MOMETASONE FUROATE] (C - Psoriasis - n/a - [n/a - n/a - Cutaneous])	
EU-EC- 10009646885	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009646886	10/08/2021	Spontaneous		l •	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Recovering/Resolving -),	COMIRNATY	Not reported	ICSR
										Respiratory tract irritation (n/a - Not Recovered/Not Resolved -),	not changed - [n/a - 1{DF} - n/a])		
										Rhinorrhoea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009646891	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovering/Resolving -)	COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009646892	10/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	[BETAMETHASONE DIPROPIONATE,	ICSR
				Area						Resolved -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	CALCIPOTRIOL, BETAMETHASONE DIPROPIONATE, CALCIPOTRIOL MONOHYDRATE, BETAMETHASONE, CALCIPOTRIOL] (C - Psoriasis - n/a - [n/a - n/a - Cutaneous]),	
												[CLOBETASOL PROPIONATE] (C - Skin disorder - n/a - [n/a - n/a - Cutaneous]),	
												[HYDROCORTISONE BUTYRATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous])	
EU-EC- 10009646893	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal discomfort (n/a - Recovering/Resolving -), Vaccination site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
										bruising (n/a - Recovering/Resolving -)			
EU-EC- 10009646895	10/08/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

U-EC-	10/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Menstrual disorder	1{DF} - n/a]) COMIRNATY	Not reported	IC
:U-EC- 10009646896	10/00/2021		Healthcare Professional	Economic	available	Years	Auolescent	геније	INO	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	not reported	10
EU-EC- 10009646897	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	[ETONOGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])	IC
										Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Dyskinesia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Hypokinesia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
:U-EC- .0009646903	10/08/2021		Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (30d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a])	
:U-EC- .0009646904	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a -	Not reported	
:U-EC- .0009646906	10/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Acne (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	
U-EC- 0009646907	10/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	
										Dizziness (n/a - Recovering/Resolving -),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Recovering/Resolving -), Headache (n/a -			
										Recovering/Resolving -), Nausea (n/a -			
										Recovering/Resolving -), Vaccination site swelling (6d -			
										Recovering/Resolving -)			
EU-EC- 10009646910	10/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	1

											not changed - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009646913	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICS
EU-EC- 10009646914	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (1d - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]),	ICS
										-)		[DERMATOPHAGOIDES PTERONYSSINUS] (C - Seasonal allergy - n/a - [n/a - n/a - Subcutaneous]),	
												[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]),	ì
												[FELIS DOMESTICUS] (C - Allergy prophylaxis - n/a - [n/a - n/a - Subcutaneous]),	
												[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Allergy prophylaxis - n/a - [n/a - n/a - Oral]),	
												[PHLEUM PRATENSE (225)] (C - Allergy prophylaxis - n/a - [n/a - n/a - Subcutaneous]),	
												[PHLEUM PRATENSE (225)] (C - Seasonal allergy - n/a - [n/a - n/a - Subcutaneous])	
EU-EC- 10009646918	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10009646923	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
EU-EC-	10/08/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Eczema (n/a - Not	1{DF} - n/a]) COMIRNATY	 [ETHINYLESTRADIOL,	ICSF
10009646926	10/06/2021	Sportaneous	Professional	Economic Area	available	Years	Adolescent	Temale	INO	Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral])	
EU-EC- 10009646936	10/08/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
EU-EC- 10009646938	10/08/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a -	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF
10009040936			Professional		available	leais				-), Cough (n/a - Recovering/Resolving	COVID-19 immunisation - Unknown - [n/a -		
										Headache (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Rash (n/a - Recovering/Resolving -)			
EU-EC- 10009646939	10/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose	Not reported	ICSF
										Anosmia (1d - Recovered/Resolved -),	not changed - [n/a - 1{DF} - n/a])		
										Influenza (9d - Recovered/Resolved -),			
										Vaccination site pain (2d - Recovered/Resolved -)			
EU-EC- 10009646943	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
											1{DF} - n/a])		

10000646000		I	Hoalthaana	Economic	available	Voore	I	I		Not Possyored /Not	TOZINAMEDANI (C	ETHINVI ECTRADIOL LACTOCE	:
10009646999			Healthcare Professional		available	Years				Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	ETHINYLESTRADIOL, LACTOSE MONOHYDRATE] (C - Polycystic ovaries - Not applicable - [n/a - n/a - n/a])	
EU-EC- 10009647667	10/08/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Abdominal pain (n/a	[TOZINAMERAN] (S - n/a - Unknown - [n/a	Not reported	ICS
10009047007			Froressional	Area	available	lears	Specified			Recovered/Resolved	- n/a - n/a])		
										Dizziness (1d - Recovered/Resolved -),			
										Hyperhidrosis (n/a - Recovered/Resolved -),			
										Pallor (n/a - Recovered/Resolved -),			
										Syncope (n/a - Recovered/Resolved -)			
EU-EC- 10009625188	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac flutter (n/a - Recovered/Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	COSENTYX [SECUKINUMAB] (C - n/a - n/a - [n/a - n/a - Subcutaneous]),	ICS
										Condition), Pallor (n/a - Recovered/Resolved -),	applicable - [1d - n/a - n/a])	[BISACODYL, DOCUSATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),]
										Palpitations (n/a - Unknown -)		[CELECOXIB] (C - Arthritis - n/a - [n/a - 200mg - Oral]),	
												[CLINDAMYCIN, BENZOYL PEROXIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[COLECALCIFEROL] (C - n/a - n/a - [n/a - 1000[iU] - Oral]), [DICLOFENAC POTASSIUM] (C	
												- n/a - n/a - [n/a - n/a - Topical]), [LORATADINE] (C - n/a - n/a -	
												[n/a - 10mg - Oral]), [PREDNISONE] (C - n/a - n/a -	
												[n/a - 5mg - Oral]), [SENNA ALEXANDRIAN] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10009625708	09/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
										Head discomfort (n/a	- 11/4])		
										Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Migraine (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
										Timportant Condition			

30.11.2022 1	2.40							IXuIII	-IIIE L	isting Report			
			Professional	Area						-), Chills (1d - Recovered/Resolved -),	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Dysmenorrhoea (1d - Recovered/Resolved -),			
										Fatigue (1d - Recovered/Resolved -),			
										Headache (1d - Recovered/Resolved -),			
										Malaise (1d - Recovered/Resolved -),			
										Myalgia (1d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10009627406	09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	маю	No	Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009627512	09/08/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Economic Area						Loss of	COVID-19 immunisation - Not applicable - [n/a - n/a		
										consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	- n/a])		
										Muscle rigidity (0d - Recovered/Resolved -),			
										Presyncope (n/a - Recovered/Resolved -)			
EU-EC- 10009627615	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	- n/a])		
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Photophobia (n/a - Unknown -			
										Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10009628172	09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (11d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a 3mL - n/a])	Not reported	ICSR
										Menstruation irregular (0d - Recovered/Resolved -)			
EU-EC- 10009628214	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	[MEDROXYPROGESTERONE ACETATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Malaise (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Nausea (n/a - Recovering/Resolving -),			
										Rash (n/a -			

12.70	ı			ı		ı			isting report	ı	1	
									Recovering/Resolving -)			
09/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
									Dizziness (n/a - Recovering/Resolving -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
									Fatigue (1d - Recovered/Resolved -),			
									Headache (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 -),			
00/00/2021	Casabanasia	I laalik aa sa	F	Net	12.17	A delegant	Mala	No	Nausea (n/a - Not Recovered/Not Resolved -)	COMIDNATY	Networked	Tech
09/08/2021	Spontaneous			available	Years	Adolescent	Male	INO	Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSF
09/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a	[MOMETASONE FUROATE] (C - n/a - n/a -)	ICSF
									Injection site pain (n/a - Not Recovered/Not Resolved -),	3mL - n/a])		
									Nausea (n/a - Not Recovered/Not Resolved -)			
09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
09/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (1d - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
									Menstruation irregular (1d - Unknown -)			
09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSE
09/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Unknown - Life Threatening),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSF
									Cardiac arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition),	- n/a])		
									Loss of consciousness (10h - Recovered/Resolved - Life Threatening, Other Medically Important Condition),			
									Lymphoma (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
									Pericardial effusion (n/a - Unknown - Life Threatening,			
	09/08/2021 09/08/2021 09/08/2021	09/08/2021 Spontaneous 09/08/2021 Spontaneous 09/08/2021 Spontaneous 09/08/2021 Spontaneous 09/08/2021 Spontaneous 09/08/2021 Spontaneous	Professional Professional Professional Professional Spontaneous Healthcare Professional Professional Spontaneous Healthcare Professional Spontaneous Healthcare Professional Spontaneous Healthcare Professional Spontaneous Healthcare Professional	Healthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Reconomic Reconomic Realthcare Professional Reconomic Recono	Healthcare Professional Profess	Healthcare Professional Economic Area Poly 1 Professional Economic Area Poly 1 Professional Economic Professional Economic Area Poly 2 Professional Economic Professional Economic Area Poly 2 Professional Economic Professional Economic Area Poly 2 Professional Economic Professional Economic Area Poly 3 Professional Economic Professional Economic Professional Economic Area Poly 3 Professional Economic Professional Professional Economic Professional Professional Economic Professional Economic Professional Professional Economic Professional Professional Economic Professional Professional Economic Professional Profess	Healthcare Professional Area Buropean Not Economic Area Not Specified Professional European Area Not Healthcare Professional Area Not Years Specified Professional Economic Area Not Healthcare Professional Area Not Years Specified Professional Area Not Years Specified Not Years Specified Not Years Specified Professional Area Not Years Specified Not Not Years Specified Not Not Years Specified Not Not Years Specified Not	Healthcare Professional Professional Professional Professional Professional Professional Professional Professional Security Professional Professional Security Professional Professional Security Professional Profes	Healthcare European Not Healthcare European Not Healthcare European Not Healthcare European Not Non Healthcare European Not Non Healthcare European Not Non Healthcare European Not Non Non Healthcare European Not Non Non	Sportameous Sportameous Professional Professional Professional Sportameous S	99/08/2012 Sportameous Peatherness Recovered Note R	

	12.10			1			1	ı (dir		listing report	1	ı	
										(n/a - Unknown - Life Threatening, Other Medically Important Condition)			
EU-EC- 10009631011	09/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Medically Important Condition)			
EU-EC- 10009631391	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009631613	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009631662	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (3d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009631791	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009631905	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (3d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -), Syncope (1d - Recovered/Resolved -), Vertigo (3d - Recovered/Resolved -), Vision blurred (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009631909	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009631931	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)		Not reported	ICSR
EU-EC- 10009631950		Spontaneous	Professional	Area	Not available Not available	12-17 Years	Adolescent		No	Diarrhoea (1d - Recovered/Resolved -), Gastrointestinal pain (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -) Urticaria (n/a - Recoverina/Resolvina Resolvina	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported Not reported	ICSR
EU-EC- 10009631952	09/08/2021	Spontaneous		Area European Economic	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a -) Tonsillitis (n/a -	COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
										Recovering/Resolving -), Urinary tract infection (n/a - Recovering/Resolving -)			

0.11.2022 1	2.40							IXuII	LIIIE I	isting Report			
EU-EC- 10009632095	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Unknown -), Pain in extremity (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009632098	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Abdominal pain (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009632130	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not amplicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009632131	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{OF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009632150	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009632493	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/Resolving/		Not reported	ICSR
EU-EC- 10009632501	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Abdominal pain lower (15d - Recovered/Resolved -), Intermenstrual bleeding (15d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009632527	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10009632718	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (2d - Recovered/Resolved -), Erythema (n/a - Not Recovered/Not Resolved -), Extensive swelling of vaccinated limb (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Peripheral swelling (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Rash papular (n/a - Not Recovered/Not Resolved -), Rash papular (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- 10009632907	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR	Not reported	ICSR

0.11.2022 1	2.40							ixuii	LIIIE L	isting Report			
											INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10009634355	09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 1{DF} - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009634426	09/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10009634434	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vision blurred (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009634436	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Swelling face (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009634448	09/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Recovered/Not Resolved -), Pruritus (n/a - Recovering/Resolving	1{DF} - n/a])		
EU-EC- 10009634451	09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
EU-EC- 10009634455	09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -),	1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),	immunisation - Dose not changed - [n/a - 1{DF} - n/a])		
										Headache (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vaccination site swelling (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009634456	09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Muscular weakness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
										Vaccination site swelling (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a])		
EU-EC- 10009634458	09/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose	Not reported	ICSR

0.11.2022 1	2.40							· (Gii		isting Report			
										Chest discomfort (n/a - Not Recovered/Not Resolved -),	not changed - [n/a - 1{DF} - n/a])		
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009634459	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	CIRCADIN [MELATONIN] (C - Insomnia - n/a - [n/a - n/a - Oral]),	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])	[HYDROXYCHLOROQUINE SULFATE] (C - n/a - n/a - [n/a - n/a - Oral]),	
										Nausea (n/a - Not Recovered/Not Resolved -),		[ISPAGHULA HUSK] (C - n/a - n/a - [n/a - n/a - Oral]),	
										Pyrexia (n/a - Not Recovered/Not Resolved -)		[NAPROXEN] (C - Dysmenorrhoea - n/a - [n/a - n/a - Oral]),	
										,		[PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]),	
												[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]),	
												[VITAMIN D, CALCIUM] (C - n/a - n/a - [n/a - n/a - Oral])	
EU-EC- 10009634461	09/08/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSR
EU-EC-	09/08/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Swelling face (n/a -	1{DF} - n/a]) COMIRNATY	Not reported	ICSR
10009634464			Healthcare Professional	Economic Area	available	Years				Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -		
EU-EC-	09/08/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Mobility decreased	1{DF} - n/a]) COMIRNATY	Not reported	ICSR
10009634474			Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -		
										Vaccination site pain (n/a - Not Recovered/Not Resolved -),	1{DF} - Intramuscular])		
										Vaccination site swelling (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009634476	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009634480	09/08/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Ma l e	No	Cough (n/a - Recovering/Resolving	Intramuscular]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						Dizziness (n/a - Not Recovered/Not Resolved -),	COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])		
										Headache (n/a - Recovering/Resolving -)			
EU-EC- 10009634481	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pharyngeal swelling (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009634487	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose	AVAMYS [FLUTICASONE FUROATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]),	ICSR
											not changed - [n/a - 1{DF} - n/a])	[ADAPALENE, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - n/a - Cutaneous]),	
												[CLINDAMYCIN PHOSPHATE, TRETINOIN, CLINDAMYCIN, TRETINOIN] (C - Acne - n/a - [n/a - n/a - Cutaneous]),	
												[HYDROCORTISONE BUTYRATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous])	

30.11.2022	12.40							IXuII	LIIIE I	isting Report			
EU-EC- 10009634493		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (4d - Recovered/Resolved -), Menstrual disorder (n/a - Recovering/Resolving -), Nausea (1d - Recovered/Resolved -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pain (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved - Recovered/Resolved		Not reported	ICSR
EU-EC- 10009634495		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Lip swelling (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009634501		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash erythematous (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009634512		Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009634513		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymph node pain (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -)	immunisation - Not applicable - [n/a - 1{DF} - n/a])	GARDASIL 9 [HUMAN PAPILLOMAVIRUS TYPE 31 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 33 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 45 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 45 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 52 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 58 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 58 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN -	ICSR

												TYPE 6 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, AMORPHOUS ALUMINIUM HYDROXYPHOSPHATE SULPHATE] (C - Human papilloma virus immunisation - n/a - [n/a - n/a - Intramuscular]), [FEXOFENADINE,	
												FEXOFENADINE HYDROCHLORIDE] (C - Urticaria - n/a - [n/a - n/a - Oral])	
EU-EC- 10009634611	09/08/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[SALBUTAMOL SULFATE] (C - Hypersensitivity - Dose not changed - [n/a - n/a - Other])	ICS
EU-EC- 10009634999	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved -), Vision blurred (n/a -	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICS
										Not Recovered/Not Resolved -)			
10009635003		Spontaneous Spontaneous	Professional	European Economic Area European	Not available	12-17 Years 12-17	Not Specified Not	Male Female	No No	Syncope (1d - Recovered/Resolved -) Chills (n/a -	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) COMIRNATY	Not reported	ICS
10009624397	08/08/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Specified	remale	INO	Recovering/Resolving -), Headache (n/a - Recovering/Resolving -),		Not reported	ICS
										Hypoaesthesia (n/a - Recovering/Resolving -), Sensitive skin (n/a - Recovering/Resolving -)			
EU-EC- 10009624540	08/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-), Chills (1d - Recovered/Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	AVAMYS 27.5 MICROGRAMS/SPRAY NASAL SPRAY SUSPENSION [FLUTICASONE FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a - n/a])	ICS
EU-EC- 10009624561	08/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Chills (n/a - Recovering/Resolving -), Injection site pain (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10009624655	08/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICS

).11.2022 1	2.48							Run	Line i	isting Report			
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10009624767	08/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Vaccination site lymphadenopathy (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC-	07/08/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Recovered/Not Resolved -) Chest pain (n/a -	COMIRNATY	[ATENOLOL, ATENOLOL BP] (C	īCS
0009619467	07,00,2021	opolitali e da	Professional	Economic Area	available	Years	Specified	, cinaje		Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	- Tachycardía paroxysmal - n/a - [n/a - 25mg - Oral])	
										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10009619504	07/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICS
EU-EC- 10009621453	07/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-), Pyrexia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19] immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICS
EU-EC- 10009621462	07/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Chills (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
EU-EC- 10009621506	07/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Headache (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Lacrimation increased (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported	ICS
										Hospitalisation), Paraesthesia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC- 10009621950	07/08/2021	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 -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU EC	07/08/2021	Chontanoous	Non	Europoan	Not	12 17	Not	Malo	No	- Not Recovered/Not Resolved -)	COMIDNATY	Not reported	ICS
EU-EC- 10009623412	07/00/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	100
EU-EC- 10009623586	07/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	RELVAR ELLIPTA 92 MICROGRAMS/22 MICROGRAMS INHALATION POWDER, PRE-DISPENSED [FLUTICASONE FUROATE, VILANTEROL] (C - n/a - n/a - [n/a - n/a	ICS
EU-EC- 10009623972	07/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICS

J.11.2022 1								, IXUII	- -	isting Report	1	1	
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10009607986	06/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
										Vertigo (2d - Recovered/Resolved -)			
EU-EC- 10009608762	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling cold (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										-), Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10009609125	06/08/2021	Spontaneous	Non Healthcare Professional	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 - [n/a - n/a	Not reported	ICSR
										Extrasystoles (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	- n/a])		
										Heart rate irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009610308	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10009610442	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10009610713	06/08/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Clonic convulsion (n/a - 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- 10009610972	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ageusia (n/a - Recovered/Resolved -), Anaphylactic reaction (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										-), Anaphylactoid reaction (2d - Recovered/Resolved -),			
										Aphthous ulcer (7d - Recovered/Resolved -), Dyspnoea (n/a -			

30.11.2022 1	12.48							Run	Line L	isting Report			
										Recovered/Resolved -), Hypoaesthesia oral			
										(n/a - Recovered/Resolved -),			
										Swelling face (2d - Recovered/Resolved -)			
EU-EC- 10009611371	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (7d - Recovered/Resolved -), Fatique (7d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL -	Not reported	ICSR
										Recovered/Resolved -), Headache (7d -	Intramuscular])		
										Recovered/Resolved -), Pyrexia (7d - Recovered/Resolved			
										Syncope (n/a - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10009611378	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Haematoma (4d - Recovering/Resolving -)	(NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10009611706	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rhabdomyolysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	.3mL - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009611743	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Rash pruritic (n/a - Recovering/Resolving -)			
EU-EC- 10009611809	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009611836	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Oropharyngeal pain (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10009612028	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Ma l e	No	Cold sweat (n/a - Recovered/Resolved -), Nausea (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	06/09/2021	Chontanoous	Hoaltheara	Europoan	Not	12-17	Adoloscopt	Malo	No	Recovered/Resolved -) SARS-CoV-2 test	COMIDNATY	Not reported	ICSR
10009613590	06/08/2021	Spontaneous	Professional	European Economic Area	Not available	Years	Adolescent	маје	No	positive (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	<u>ICSK</u>
										Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10009613594	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pruritus (n/a - Recovered/Resolved -),			
										Skin reaction (n/a - Recovered/Resolved -), Swelling (n/a -			
EU EC	06/09/2021	Cnorton	Non	Europa	Not	12.17	Adalas	Mala	No	Recovered/Resolved -)	COMIDNATY	Not reported	ICCD
EU-EC-	06/08/2021	Spontaneous	INON	European	Not	12-17	Adolescent	ма і е	No	Lymphadenopathy	COMIRNATY	Not reported	<u>ICSR</u>

.11.2022 1	2.48							Ruiti	LIIIC L	isting Report			
10009613611			Healthcare Professional	Economic Area	available	Years				(n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10009614044	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Hypotension (n/a - Recovering/Resolving - Other Medically Important Condition),	.3mL - Intramuscular])		
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
:U-EC- .0009614100	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Oropharyngeal swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ABILIFY 10 MG TABLETS [ARIPIPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICS
U-EC- 0009614137	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Unknown -), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSI
	06/00/2024	C	NI	F	N	12.17	N	FI-		Unknown -)		Not an and a	TOOL
EU-EC- 10009614184	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Chills (1d - Recovering/Resolving - Disabling),	applicable - [n/a - n/a - n/a])		
										Eating disorder (1d - Recovering/Resolving - Disabling),			
										Fatigue (1d - Recovering/Resolving - Disabling),			
										Headache (1d - Recovering/Resolving - Disabling),			
										Malaise (1d - Recovering/Resolving - Disabling),			
										Myalgia (1d - Recovering/Resolving - Disabling),			
										Nausea (1d - Recovering/Resolving - Disabling),			
										Pyrexia (1d - Recovering/Resolving - Disabling),			
										Vomiting (1d - Recovering/Resolving - Disabling)			
EU-EC- 10009614714	06/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	HUMIRA [ADALIMUMAB] (C - Crohn's disease - n/a - [n/a - n/a - n/a])	ICSF
EU-EC- 10009614743	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (10d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[DYDROGESTERONE, ESTRADIOL, DYDROGESTERONE, ESTRADIOL HEMIHYDRATE,	ICSF
				/ • • •						Asthmatic crisis (13d		ESTRADIOL, ESTRADIOL HEMIHYDRATE] (C -	
										Recovered/Resolved - Other Medically Important Condition),	1.100.110500(2.1)	Dysmenorrhoea - n/a - [n/a - n/a - Oral])	
										Choking (10d - Recovered/Resolved - Other Medically Important Condition),			
		l	1	I	I	1	1			1			
										Cough (10d - Recovered/Resolved -),			
										Recovered/Resolved			

0.11.2022 1	2.40							Kuli	Lille L	isting Report			
										Influenza like illness (12d - Recovered/Resolved -),			
										Malaise (297h - Recovered/Resolved -),			
										Oxygen saturation decreased (10d - Recovered/Resolved - Other Medically Important Condition),			
										Pain (13d - Recovered/Resolved -),			
										Vaccination site pain (294h - Recovered/Resolved			
EU-EC- 10009615630	06/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Extensive swelling of vaccinated limb (n/a - Unknown - Disabling),	immunisation - Not applicable - [n/a - n/a - n/a])		
										Fatigue (n/a - Unknown - Disabling),			
										Headache (n/a - Unknown - Disabling),			
										Malaise (n/a - Unknown - Disabling),			
										Myalgia (n/a - Unknown - Disabling),			
										Nausea (n/a - Unknown - Disabling),			
										Pyrexia (n/a - Unknown - Disabling)			
EU-EC- 10009615891	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Migraine with aura (5h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Sensory loss (5h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10009615936	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009616128	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nasopharyngitis (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Productive cough (n/a - Not Recovered/Not Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10009616148	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009616188	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pain in extremity (n/a - Recovering/Resolving			
EU-EC- 10009616195	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Anxiety (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

0.11.2022 1	2.40							Ruii	LIIIe L	isting Report			
EU-EC- 10009616198	06/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved -), Menstruation delayed (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009616204	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (3d - Recovered/Resolved -), Dizziness (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Vomiting (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009616323	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Salivary hypersecretion (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009616685	06/08/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Costochondritis (4d - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Other Medically	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10009616942	06/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Extensive swelling of vaccinated limb (n/a - Unknown -), Lymphadenitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
10009617021		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Bradycardia (n/a - Recovering/Resolving - Life Threatening), Fatigue (n/a - Recovering/Resolving -), Hypopnoea (n/a - Recovering/Resolving - Life Threatening), Status epilepticus (n/a - Recovering/Resolving - Life Threatening), Unresponsive to stimuli (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	KEPPRA 500 MG FILM-COATED TABLETS [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PHENOBARBITAL, SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [VALPROIC ACID, SODIUM, VALPROIC ACID, SODIUM VALPROATE] (C - n/a - n/a - n/a - [n/a - n/a - n/a - [n/a - n/a - n/a - n/a])	
10009617941		Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Not Specified	Female	No	Kidney infection (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10009619120	06/08/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Tremor (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[DESOGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral])	ICSR
EU-EC- 10009619137	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Presyncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

								, tuii		isting report			
										Unknown - Caused/Prolonged			
EU-EC- 10009619144	06/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Decreased appetite (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a -	Not reported	ICSF
										Dizziness (n/a - Recovering/Resolving -),	1{DF} - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Feeling of body temperature change (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Pain (n/a - Recovering/Resolving -)			
EU-EC- 10009619149	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10009619162	06/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypoaesthesia (2d - Recovered/Resolved -), Paraesthesia (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Pyrexia (2d - Recovered/Resolved -),			
										Vomiting (2d - Recovered/Resolved -)			
EU-EC- 10009619909	06/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pruritus (n/a - Not Recovered/Not Resolved -),	applicable - [1d - 1{DF} - Unknown])		
EU-EC-	06/08/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -) Migraine (1d -	COMIRNATY	Not reported	ICSR
10009619927	00,00,2021	Sportaneous	Professional		available	Years	nadieses.	Cinale		Recovered/Resolved -), Presyncope (1d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	The Topolica	<u>10010</u>
EU-EC- 10009619929	06/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009619939	06/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009595598	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Respiratory fatigue (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10009595782	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Menstruation irregular (n/a - Not Recovered/Not Resolved -)	Intramuscular])		
EU-EC- 10009595850	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (0d - Recovered/Resolved -), Dizziness (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Hyperhidrosis (0d -			
										Recovered/Resolved			

1.11.2022 1	2.40							Run	Line L	Isling Report			
										Presyncope (0d - Recovered/Resolved -)			
EU-EC- 10009595863	05/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Rash (0d - Recovered/Resolved -), Sensation of foreign body (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10009595882	05/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Hypotension (n/a - Recovering/Resolving -), Presyncope (n/a - Recovering/Resolving	COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009595913	05/08/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 1.0009597760	05/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009597782	05/08/2021	Spontaneous	Healthcare		Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009598058	05/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Electrocardiogram abnormal (n/a - Unknown -), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Unknown - Caused/Prolonged Caused/Prolonged Caused/Prolonged Caused/Prolonged Caused/Prolonged Caused/Prolonged Caused/Prolonged Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009599250	05/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Burning sensation (n/a - Not Recovered/Not Resolved - Disabling), Hyperventilation (n/a - Not Resolved - Disabling), Seizure (n/a - Not Recovered/Not Resolved - Disabling), Seizure (n/a - Not Recovered/Not Resolved - Disabling, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10009599732	05/08/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adult	Male	No	Important Condition) Generalised tonic- clonic seizure (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - Dose not changed - [n/a - n/a - n/a]), [VALPROIC ACID, SODIUM, VALPROIC ACID, SODIUM VALPROATE] (C - n/a - Dose increased - [n/a - n/a])	ICSR
EU-EC- 10009600413	05/08/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	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 Resolved -), Myalgia (n/a - 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])	ICSR
EU-EC- 10009600866	05/08/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Anaphylactic reaction (0d - Recovered/Resolved -) Recovered/Resolved - Other Medically Important Condition), Anaphylactoid reaction (0d - Recovered/Resolved - Other Medically Important Condition), Circulatory collapse (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

Contraction of Cont		22 12.40							. IXUII L		isting report			
Eu-EC GEOLOGIC Spentaneous Res Res September Septemb											Important			
### Biode (6) Control											Recovered/Resolved			
BU-BC CS(BC221 Spintaneous New Performance New Performan											disorder (0d - Recovered/Resolved - Other Medically Important			
No. Processor											Recovered/Resolved - Other Medically Important			
											Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 1009/900397 Sportaneous Name Realmoure Realmour			. Spontaneous	Healthcare	Economic			Adolescent		No	(n/a - Not Recovered/Not	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
EU-EC- 1009/G01201 Sportaneous Institute European Not Professional			Spontaneous	Healthcare	Economic			Adolescent		No	(n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
E1-EC- 100096009992 Spontaneous Healthcare Professional Economic Area Not Years Specified Female Not Area Are			Spontaneous	Healthcare	Economic				Male	No	Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC_1009503992 Sportaneous Healthcare Non Professional European Area Non Professional European Non Non Professional European Non Non Professional European Non Non Professional European Non Non Non Professional European Non Non Non Non Non Non Non Non Non No											reaction (3d - Recovering/Resolving	applicable - [n/a - n/a		
Professional European Area Professional European Area Specified														
Chest pain (n/a – Unknown –), Patique (n/a – Unknown –), Headdanke (n/a – Unknown –), Headdanke (n/a – Unknown –), Pyrola (n/			Spontaneous		European Economic				Female	No	- Recovered/Resolved - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a	HYDROCHLORIDE, IBUPROFEN, IBUPROFEN] (C -	ICSR
EU-EC- 10009601010 OS/08/2021 Spontaneous Healthcare Non Professional Economic Area											Chest pain (n/a -	,		
Unknown -), Headache (n/a - Unknown -), Headache (n/a - Unknown -), Pain (n/a - Unknown -),														
EU-EC- 10009601010 EU-EC- 10009601010 EU-EC- 10009601010 Spontaneous Healthcare Non Professional European Economic Area														
EU-EC- 1009601010 D5/08/2021 Spontaneous Healthcare Professional European E														
EU-EC- 1009601010 Spontaneous Healthcare Professional European Eur														
EU-EC- 1009601010 EU-EC- 10009601010 EU-EC- 10009601010 EU-EC- 10009601010 EU-EC- 10009601010 EU-EC- 10009601010 Forfessional European Economic Area Healthcare Professional European Economic Area European Economic Area Non Professional European Economic Area Non European Economic Area Non Recovered/Resolved - J, C-reactive protein increased (n/a - Recovered/Resolved - J) Cardiac infection (n/a - Not Resolved - Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved + C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - C-aused/Prolonged Hospitalisation, Other Medically Important Condition)														
EU-EC- 1009601010														
Professional European Economic Area Professional Economic Area Professional Economic Area Professional European Economic Area Professional Economic Area Prof	EU EC	05/09/2021	Chantanaous	Hoaltheara	Non	Not	12 17	Not	Fomalo	No	Unknown -)	TOZINAMEDANI	VINEDET FANAVINDAL (C	ICSR
C-reactive protein increased (n/a - Recovered/Resolved -), Recovered/Resolved -), Cardiac infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Recovered/Polonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically			. Spontaneous		European Economic				remale	INO	peptide increased (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Myocarditis - n/a - [n/a - 100mg - Subcutaneous]),	ICSK
Cardiac infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged HOSpitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged HOSpitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged HOSpitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged HOSpitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged HOSpitalisation, Other Medically											C-reactive protein increased (n/a - Recovered/Resolved		DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a -	
Condition), Chest pain (n/a - Recovered/Resolved											Cardiac infection (n/a - Not Recovered/Not		SALMETEROL XINAFOATE] (Ć - Asthma - n/a - [n/a - 42ug - Nasal]),	
Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Other Medically Condition, Other Medically Other Medically											Medically Important Condition),		MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - 5mg -	
Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically											Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important		HYDROCHLORIDE] (C - Depression - n/a - [n/a -	
											Recovered/Resolved - Caused/Prolonged Hospitalisation,			

U.11.2U22 1 '	.40							- Kuli	LIII E L	Isling Report	ı	ı	
										Condition), Inflammatory marker increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10009601110	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pallor (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10009601861	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009602651	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009602676	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	ABILIFY [ARIPIPRAZOLE] (C - n/a - n/a -)	ICSR
EU-EC- 10009602677	05/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10009602730	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Face oedema (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving	COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
EU-EC- 10009602766	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (15d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009602820	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10009602849	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-), Urticaria (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10009602862	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) Hypotension (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving -),	COVID-19 immunisation - Drug withdrawn - [1d - .3mL -	Not reported	ICSR
										Malaise (n/a - Recovering/Resolving -)			
EU-EC- 10009603214	05/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Agitation (n/a - Unknown -), Autoscopy (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not			
										Recovered/Not Resolved -),			

0.11.2022 1	2.48							Run	Line L	isting Report			
										Heart rate decreased (n/a - Unknown - Other Medically Important Condition),			
										Hypersensitivity (n/a - Unknown -),			
										Inner ear disorder (n/a - Recovered/Resolved -)			
EU-EC- 10009604884	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10009605476	05/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Unknown -), Headache (n/a - Unknown -), Heart rate increased (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Unknown -)			
EU-EC- 10009606143	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009606144	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Swelling face (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009606152	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypersensitivity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009606161	05/08/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10009606411	05/08/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY	Not reported	ICSR
EU-EC- 10009606426	05/08/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY	Not reported	ICSR
EU-EC- 10009606459	05/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

Rows 12501 - 13000

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