Line Listing Report Time run: 30/11/2022 03:49:59

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10011523534	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011523611	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -), Rhinorrhoea (n/a - Recovered/Resolved -), Sleep disorder (n/a - Recovered/Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011524044		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Diplopia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Strabismus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011524084	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011524188	07/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011524987	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Recovered/Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011525040	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Injection site pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - n/a])	Not reported	ICSR
EU-EC- 10011525784	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Burning sensation (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

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	EU-EC- 10011525789	07/02/2022	Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE, CIPROFLOXACIN, HYDROCORTISONE] (C - Ear infection - n/a - [n/a - n/a - n/a]),	ICSR
													[CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
													[FLUTICASONE PROPIONATE] (C - Asthma prophylaxis - n/a - [n/a - n/a - Respiratory (inhalation)]),	
													[MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a - Oral]),	
													[PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]),	
													[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]),	
													[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	
	EU-EC- 10011525791	07/02/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE, CIPROFLOXACIN, HYDROCORTISONE] (C - Ear infection - n/a - [n/a - n/a - n/a]),	ICSR
													[CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
													[FLUTICASONE PROPIONATE] (C - Asthma prophylaxis - n/a - [n/a - n/a - Respiratory (inhalation)]),	
													[MEBENDAZOLE] (C - Enterobiasis - n/a - [n/a - n/a - Oral]),	
													[PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]),	
													[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]),	
	FILES	07/02/2025	Consti	1102		Nex		Child		N		COMPANY	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	1005
	EU-EC- 10011525799	W//WZ/Z0ZZ	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ANHYDROUS FUSIDIC ACID, FUSIDIC ACID, FUSIDIC ACID PH. EUR., SODIUM FUSIDATE, SODIUM FUSIDATE PH. EUR.] (C - Skin infection -	<u>ICSR</u>

												n/a - [n/a - n/a - Cutaneous])	
EU-EC- 10011525817	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving -), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011526114	07/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Recovering/Resolving -) Epistaxis (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
											immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10011526142	07/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Complicated appendicitis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011527038	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Rash (16d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011527275	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10011527290	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10011527342	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Arrhythmia (16d - Recovering/Resolving -), Chest pain (16d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (16d - Recovering/Resolving -), Painful respiration (16d -			
										Recovering/Resolving -), Tachycardia (16d - Recovering/Resolving			
EU-EC- 10011527633	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	-) Fatigue (12d - Not Recovered/Not Resolved -), Headache (12d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza like illness (12d - Not Recovered/Not Resolved -),			
										Injection site pain (12d - Not Recovered/Not Resolved -),			
										Limb discomfort (12d - Not Recovered/Not Resolved -), Myalgia (12d - Not			
										Recovered/Not Resolved -), Oropharyngeal pain (12d - Not Recovered/Not			
EU-EC- 10011527650	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Male	No	Resolved -) Oral herpes (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10011527657	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Cold sweat (12d - Recovered/Resolved -), Headache (12d - Recovered/Resolved -), Lymphadenopathy (12d - Recovered/Resolved -), Malaise (12d - Recovered/Resolved -), Nausea (12d - Recovered/Resolved -), Urticaria (12d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011527738	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Elderly	Male	No	Fatigue (8d - Not Recovered/Not Resolved -), Myalgia (8d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011528027	07/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Oral herpes (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011528071		Spontaneous	Healthcare Professional		Not available	3-11 Years	Adult	Female	No	Malaise (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011507373	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011507406	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011507561	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Rash (n/a - Not Recovered/Not Resolved -), Skin lesion (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC- 10011510125	06/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Not Specified	No	Malaise (30min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - n/a])	Not reported	ICSR
EU-EC- 10011510544	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011510549	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011510552	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (7d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011510554	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (23d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011510716	06/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	Yes	Seizure (5min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Od - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011510846	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (2d - Recovered/Resolved -), Fatigue (0d - Unknown -), Headache (2d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC- 10011510852	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain lower (n/a - Not Recovered Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSF
EU-EC- 10011510853	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Resolved -) Influenza (1d - Recovered/Resolved -), Influenza (n/a - Unknown -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Menstrual disorder (1d - Recovered/Resolved -), Menstrual disorder			
EU-EC- 10011510862	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	(n/a - Unknown -) Petechiae (0d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Pyrexia (n/a - Recovering/Resolving -), Rash (0d - Recovering/Resolving			
										Rash erythematous (0d - Recovering/Resolving -)			
EU-EC- 10011510863	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Asthenia (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10011510866	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -), Influenza like illness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011510875	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Sleep disorder (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011510879	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Asthenia (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011510887	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Myalgia (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011510888	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not			
										Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not			
EU-EC- 10011510895	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Resolved -) Intermenstrual bleeding (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Vomiting (2d - Recovered/Resolved -)			
EU-EC- 10011510898	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (2d - Recovering/Resolving -), Nasopharyngitis (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Pyrexia (2d - Recovering/Resolving -)			
EU-EC- 10011510900	06/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSF

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			Professional	Area						-), Pyrexia (1d -	Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-	06/02/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Recovered/Resolved -) Chills (1d - Unknown	COMIRNATY	Not reported	ICSR
10011510901	00/02/2022	Spontaneous	Healthcare Professional	Economic	available	Years	Ciliu	Male	INO	-), Erythema (1d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSK
										Unknown -), Influenza like illness	[:,, = .,, =],		
										(1d - Unknown -), Pyrexia (1d -			
EU-EC- 10011510908	06/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Unknown -) Dizziness (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional							Resolved -), Fatigue (n/a - Not Recovered/Not	Îmmunisation - n/a - [n/a - n/a - n/a])		
										Resolved -), Headache (n/a - Not Recovered/Not			
										Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (0d - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011510952	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (5d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011510958	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Back pain (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Fatigue (13d - Recovering/Resolving -),	[[174 - 174 - 174]]		
										Headache (12d - Recovered/Resolved -),			
										Nausea (7d - Recovered/Resolved -)			
EU-EC- 10011510963	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (3d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	<u>ICSR</u>
										Fatigue (2d - Recovered/Resolved -),	[n/a - n/a - n/a])		
										Injection site pain (3d - Not Recovered/Not			
FIL F0	05/02/2022	C	Nico		NI - I	2.44	Child	NA - 1 -	N1 -	Resolved -)	COMPNIATIO	Not an artist	TOOD
EU-EC- 10011510964	06/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Alopecia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011510969	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Influenza like illness (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain			
										Recovered/Resolved			
										Lymphadenopathy (4d - Recovered/Resolved			
EU-EC- 10011510978	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Nasopharyngitis (1d - Not Recovered/Not Resolved -),	[n/a - n/a - n/a])		
										Oropharyngeal pain (1d - Not Recovered/Not			
EU-EC- 10011511015	06/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Female	No	Resolved -) Erythema (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional				Specificu			Resolved -),	[

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										Rash (n/a - Not Recovered/Not Resolved -)	Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011511067	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011511070	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (0d - Recovered/Resolved -), Rash (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										-)			
EU-EC- 10011511072	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Influenza like illness (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011511083	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Nausea (1d - Recovered/Resolved -), Pyrexia (32d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										-), Vomiting (0d - Recovered/Resolved			
EU-EC- 10011511086	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011511134	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011511355	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
	05/00/0000			 -						Abdominal pain (n/a - Unknown -)	applicable - [n/a - 1{DF} - n/a])	[D.D.D.D.D.D.D.D.D.D.D.D.D.D.D.D.D.D.D.	1000
EU-EC- 10011512100	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
										Recovering/Resolving -), Malaise (n/a - Not Recovered/Not	1{DF} - n/a])		
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011512204	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011512507	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (10d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (18d - Not Recovered/Not Resolved -),			
										Headache (11d - Not Recovered/Not Resolved -),			
										Pain in extremity (18d - Not Recovered/Not Resolved -),			
										Paraesthesia (16d - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011512510	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (30d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011512527	06/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Sleep terror (0d - Recovered/Resolved -)			
EU-EC- 10011512529	06/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Vaccination site pain (0d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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No. No. No. No.				Professional	Area					-),			
ELEC. 1001512535 10022022 Sportlateous No. European Not. Control Not. Control No. Cont		06/02/2022	Spontaneous	Healthcare	Economic		Child	Female	No	(2d - Recovering/Resolving -), Headache (2d - Recovering/Resolving	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
Paul District Paul Distric										Recovering/Resolving -)			
EUROPE Professional No. Professional No. Professional		06/02/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Recovered/Resolved -), Urticaria (1d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	<u>ICSR</u>
EU-EC- 10011512538 20/02/2022 Spontaneous Non- Healthcare European Not Professional Non- Healthcare European Not Professional Non- Professional Non- Professional Non- Not		06/02/2022	Spontaneous	Healthcare	Economic		Child	Female	No	Dyspnoea (0d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Rash (0d - Recovered/Resolved -), Syncope (0d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10011512541 06/02/2022 Spontaneous Non Healthcare Professional European Healthcare Professional Non Healthcare Professional Non Healthcare Professional Non Healthcare Not Area Not Recovering/Resolving (2d - Not Recovering/Resolving (170ZINAMERANI) (5 - 170 - (7d - (7d)) Not reported IC Not Recovering/Resolving (170ZINAMERANI) (5 - 170 - (7d)) Not reported IC Not Recovering/Resolving Not Recove		06/02/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Important Condition) Influenza like illness (2d - Recovered/Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
ELFEC- Interpretation Interpretati	_									Recovered/Resolved -)			
EU-EC- 10011512555 06/02/2022 Spontaneous Spontaneou		06/02/2022	Spontaneous	Healthcare	Economic		Child	Female	No	Recovering/Resolving -), Vaccination site pain (2d -	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10011512552		06/02/2022	Spontaneous	Healthcare	Economic		Child	Female	No	Rash (4d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 1001151253		06/02/2022	Spontaneous	Healthcare	Economic		Child	Female	No	Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site erythema (7d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
10011512560 Healthcare Professional Recovered/Resolved Profess		06/02/2022	Spontaneous	Healthcare	Economic		Child	Male	No	Headache (3d - Recovering/Resolving -), Pyrexia (3d - Recovering/Resolving -), Vaccination site swelling (3d -	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
10011512561 Healthcare Economic available Years Recovering/Resolving [TOZINAMERAN] (S -		06/02/2022	Spontaneous	Healthcare	Economic		Child	Male	No	(2d - Recovered/Resolved -), Lymphadenopathy (1d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
		06/02/2022	Spontaneous	Healthcare	Economic		Child	Female	No	Recovering/Resolving		Not reported	ICSR

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PLACE PAPE											Recovered/Resolved			
											Headache (2d - Recovered/Resolved			
EL-SC		06/02/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Recovering/Resolving -), Injection site pain (3d - Recovering/Resolving	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
ED-FC Deli 1973/2002 Sportnamenous Norm Room R		06/02/2022	Spontaneous	Healthcare	Economic			Adult		No	Bone pain (7d - Unknown -), Headache (7d -	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
ELFEC- 10011512580 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512584 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Professional Area ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Available Years ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Available Years ELFEC- 10011512586 O6/02/2022 Spontaneous Non Healthcare Economic Available Years ELFEC- 10011512586 O6/02/2022 Spontaneous Non European Not Healthcare Economic Available Years ELFEC- 10011512586 O6/02/2022 Spontaneous Non European Not Healthcare Economic Available Years ELFEC- 10011512586 O6/02/2022 Spontaneous Non European Not Healthcare Economic Available Years ELFEC- 10011512586 O6/02/2022 Spontaneous Non European Not Healthcare Economic Available Years ELFEC- 10011512587 O6/02/2022 Spontaneous Non European Not Healthcare Economic Available Years ELFEC- 10011512588 O6/02/2022 Spontaneous		06/02/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Headache (4d - Not Recovered/Not Resolved -), Influenza like illness (4d - Not Recovered/Not Resolved -), Limb discomfort (4d - Not Recovered/Not Resolved -), Malaise (4d - Not Recovered/Not Resolved -), Pyrexia (4d - Not	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
Healthcare Conomic Professional Area			-								Resolved -)			<u> </u>
ELFEC- 10011512582 2007/2022 2007/		06/02/2022	Spontaneous	Healthcare	Economic			Child	Male	No	Recovered/Resolved -), Rash (1d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
EU-EC- 10011512584 06/02/2022 Spontaneous Non lealthcare Economic Professional Not lealthcare Economic Professional Not lealthcare Economic Professional Not		06/02/2022	Spontaneous	Healthcare	Economic			Child	Female	No	(0d - Recovering/Resolving -), Pruritus (0d - Recovering/Resolving	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
EU-EC- 10011512586 06/02/2022 Spontaneous Non Healthcare Professional Area European Professional Area Not Economic Professional Area Not Specified Not Spe		06/02/2022	Spontaneous	Healthcare	Economic		1	Child	Male	No	Diarrhoea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
EU-EC- 10011512596 06/02/2022 Spontaneous Professional Distribution Professional Distribution Professional Distribution Professional Distribution Professional Distribution Professional Distribution D		06/02/2022	Spontaneous	Healthcare	Economic				Male	No	Headache (1d - Recovered/Resolved -), Vaccination site reaction (1d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSI
EU-EC- 10011512602 Spontaneous Non Healthcare Professional Realthcare Professional Recommic Recovered/Resolved -), Circulatory collapse (0d - Recovered/Resolved - Other Medically Important Condition), General physical health deterioration (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -) EU-EC- 06/02/2022 Spontaneous Non European Not 3-11 Child Male No Herpes simplex (n/a COMIRNATY Not reported IC		06/02/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Limb discomfort (n/a - Not Recovered/Not Resolved -), Seasonal allergy (n/a - Not Recovered/Not	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSI
EU-EC- 06/02/2022 Spontaneous Non European Not 3-11 Child Male No Herpes simplex (n/a COMIRNATY Not reported IC		06/02/2022	Spontaneous	Healthcare	Economic			Child	Male	No	Blood pressure decreased (0d - Recovered/Resolved -), Circulatory collapse (0d - Recovered/Resolved - Other Medically Important Condition), General physical health deterioration (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved Recovered/Resolved Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSF
10011512605 Healthcare Economic available Years - Unknown -), [TOZINAMERAN] (S -	EU-EC- 10011512605	06/02/2022	Spontaneous			Not available		Child	Male	No	· /	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSI

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EU-EC- 10011512607	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Unknown -) Rash (1d - Recovering/Resolving -)	Immunisation - n/a -	Not reported	ICSR
EU-EC- 10011512611	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (0d - Recovered/Resolved -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Urticaria (0d - Recovered/Resolved -)			
EU-EC- 10011512613	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011512615	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Decreased appetite (1d - Recovering/Resolving -), Headache (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (2d - Recovered/Resolved -), Vomiting (1d - Recovering/Resolving			
EU-EC- 10011512616	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Influenza like illness (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (1d - Recovering/Resolving -)			
EU-EC- 10011512622	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011512623	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Malaise (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Panic attack (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not			
EU-EC- 10011512625	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Resolved -) Abdominal pain upper (2d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (2d - Recovering/Resolving -)			
EU-EC- 10011512627	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (1d - Not Recovered/Not Resolved -), Nausea (1d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	06/02/2022	Spontaneous		European	Not	3-11	Child	Male	No	Recovered/Not Resolved -) Headache (2d -	COMIRNATY	Not reported	ICSR
10011512628			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -), Limb discomfort (1d - Recovered/Resolved -),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Malaise (1d - Recovered/Resolved -)			
EU-EC- 10011512638	06/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Influenza (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011502688	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Swelling of eyelid (0d - Recovered/Resolved -)		Not reported	ICSR
EU-EC- 10011502823	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011503557	05/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
tne://dan.en		, ,	,							Cough (2d - Recovered/Resolved	applicable - [n/a -		10//

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EU-EC- 10011503600	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	-), Headache (2d - Recovered/Resolved -), Nasal congestion (2d - Recovered/Resolved -) Arthralgia (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a -	1{DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011506001	05/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Recovering/Resolving -) Rash (n/a - Unknown -)	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSF
EU-EC- 10011506005	05/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (n/a - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a]	Not reported	ICSF
EU-EC- 10011506014	05/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (5d - Not Recovered/Not Resolved -)	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011506037	05/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Influenza (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011506042	05/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (20d - Not Recovered/Not Resolved -), Headache (18d - Recovering/Resolving -), Malaise (20d - Not Recovered/Not Resolved -), Nausea (20d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011506058	05/02/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Male	No	Injection site pain (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011506274	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (13d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011506575	05/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Adult	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Feeling hot (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011506577	05/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Adult	Female	No	Hypoaesthesia (12d - Not Recovered/Not Resolved -), Joint swelling (12d - Not Recovered/Not Resolved -), Limb discomfort (12d - Not Recovered/Not Resolved -), Myalgia (12d - Not Recovered/Not Resolved -), Ocular icterus (12d - Not Recovered/Not Resolved -), Resolved -), Ocular icterus (12d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Paraesthesia (12d - Not Recovered/Not Resolved -),			
										Visual impairment (12d - Not Recovered/Not Resolved -)			
EU-EC- 10011506690	05/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Adnexa uteri pain (17d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Back pain (17d - Recovering/Resolving -),			
										Fatigue (17d - Recovering/Resolving -),			
										Lymphadenopathy (17d - Recovering/Resolving -),			
										Postmenopausal haemorrhage (17d - Recovering/Resolving -)			
EU-EC- 10011489575	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	<u>ICSR</u>
										Dizziness (0d - Recovered/Resolved -), Hyperhidrosis (0d -	[n/a2mL - Intramuscular])		
										Recovered/Resolved -), Hypotension (0d -			
										Recovered/Resolved -), Malaise (0d - Recovered/Resolved			
										-), Pallor (0d - Recovered/Resolved			
EU-EC- 10011489615	04/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Abdominal pain (n/a	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional							Recovering/Resolving -), Chills (n/a - Recovering/Resolving			
										-), Fatigue (n/a - Recovering/Resolving			
										-), Headache (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10011489675	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pain in extremity (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
EU-EC- 10011489843	04/02/2022	Spontaneous	Healthcare Professional	European Economic	Not available	3-11 Years	Not Specified	Male	No	Hypoaesthesia (0d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area						-)	COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])		
EU-EC- 10011489902	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Vertigo (n/a - Recovering/Resolving	immunisation - Not applicable - [n/a - .1mL - Intramuscular])		
EU-EC- 10011489904	04/02/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Pyrexia (3d - Recovered/Resolved -),	applicable - [n/a1mL - Intramuscular])		
										Somnolence (3d -			

		I	I	ı	ı	ı			, Liotin;	g report	I	I	1
										Recovered/Resolved			
EU-EC- 10011492219	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Skin irritation (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- 10011492227	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011493630	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Anxiety (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495146	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495157	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495165	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495169	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495170	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495177	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495178	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495192	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495268	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011495290	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	04/02/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Dizziness (2d -	COMIRNATY	Not reported	ICSR

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10011495300			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -), Headache (4d - Recovering/Resolving -), Injection site pain (2d - Recovered/Resolved -), Limb discomfort (1d - Recovered/Resolved -), Myalgia (2d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Resolved -)			
EU-EC- 10011495860	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (2h - Recovered/Resolved -), Diarrhoea (2h - Recovered/Resolved -), Syncope (15min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	04/02/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	-) Injection site pain	COMIRNATY	Not reported	ICSR
10011496279	04/02/2022	Spontaneous	Healthcare Professional	Economic Area	available	Years	Ciliu	Male	INO	(1d - Recovered/Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSK
EU-EC- 10011496280	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496283	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -), Injection site swelling (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10011496285	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496288	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496331	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496337	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10011496338	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Inmunisation - n/a - 1/2 - 1/	Not reported	ICSR
EU-EC- 10011496342	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10011496346	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10011496358	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a]	Not reported	ICSR
EU-EC- 10011496359	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	04/02/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	-) Injection site pain	COMIRNATY	Not reported	ICSR
10011496360			Healthcare Professional	Economic Area	available	Years				(2d - Recovered/Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011496365	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496371	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Vaccination site	Live ive ively		

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										reaction (1d - Recovered/Resolved			
EU-EC- 10011496372	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site erythema (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011496373	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496376	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496377	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011496378	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011496379	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011496380	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496382	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496385	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10011496386	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10011496400	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSE
EU-EC- 10011496401	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10011496403	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10011496405	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
	0.4 (0.0 (0.000)					2.11	CI II I			Paraesthesia (n/a - Not Recovered/Not Resolved -)			1000
EU-EC- 10011496407	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011496408	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Feeling hot (1d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Nausea (0d - Recovered/Resolved			
EU-EC- 10011496410	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (31d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496412	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10011496413	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011496414	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (62d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC- 10011496417	04/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Injection site pain (0d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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			Professional	Area						Recovered/Resolved	Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011496418	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496420	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496434	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10011496436	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011496437	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011496438	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011496440	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011496442	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496448	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496462	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496464	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site reaction (30d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496467	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496468	04/02/2022	Spontaneous		Economic	Not available	3-11 Years	Child	Female	No	Injection site erythema (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496478	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496480	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496508	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496511	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (0d - Recovered/Resolved -)	[
EU-EC- 10011496512	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496517	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496519	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011496520	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011496521	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (93d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	04/02/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	Injection site pain	COMIRNATY	Not reported	ICSR

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10011496522			Healthcare Professional	Economic Area	available	Years				(2d - Recovered/Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011496525	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
EU-EC- 10011496526	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	-) Injection site pain (0d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a]	Not reported	ICS
U-EC- 0011496528	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Injection site pain (0d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Invariant - n/a	Not reported	ICS
U-EC- 0011496529	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site erythema (2d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [7])	Not reported	ICS
EU-EC- .0011496530	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
U-EC- 0011496543	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 0011496545	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
U-EC- .0011497033	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovered/Resolved - Other Medically Important Condition), Injection site infection (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a1mL - n/a - More in ICSR])	Not reported	ICS
EU-EC- .0011497813	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
U-EC- .0011497814	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
EU-EC- 10011497815	04/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	-) Injection site pain (2d - Recovered/Resolved -)	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
:U-EC- .0011500238	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Myalgia (n/a - Recovering/Resolving -)	COMIRNATY	Not reported	ICS
U-EC- .0011500267	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a	Not reported	<u>ICS</u>
:U-EC- 0011500275	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Erythema (n/a - Recovering/Resolving -), Rash pruritic (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICS
U-EC- 0011500292	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Erythema (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICS
EU-EC- .0011500378	04/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Decreased appetite (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CYCLOPENTOLATE, CYCLOPENTOLATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [TOBRAMYCIN] (C - Eye infection - n/a - [n/a - n/a - Ophthalmic])	ICS
										Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -),			

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										Pain (n/a - Recovering/Resolving -)			
EU-EC- 10011500708	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011500727	04/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10011476441	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10011476589		Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Conjunctivitis (n/a - Recovering/Resolving - Other Medically Important Condition), Epistaxis (n/a - Recovering/Resolving - Other Medically Important Condition), Muscle spasms (n/a - Recovering/Resolving - Other Medically Important Condition), Nasal congestion (n/a - Recovering/Resolving - Other Medically Important Condition), Stupor (n/a - Recovering/Resolving - Other Medically Important Condition), Stupor (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011476602	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Angioedema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011476632	03/02/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cluster headache (6d - Recovered/Resolved -), Eye pruritus (6d - Recovered/Resolved -), Migraine (6d - Recovered/Resolved -), Nausea (6d - Recovered/Resolved -), Periorbital swelling (6d - Recovered/Resolved -), Somnolence (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011476955 EU-EC- 10011478293		Spontaneous	Professional	European Economic Area Non European Economic Area	Not available Not available	3-11 Years 3-11 Years	Not Specified Not Specified	Male	No	Pruritus (5d - Recovered/Resolved -), Rash pruritic (5d - Recovered/Resolved -) COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported Not reported	ICSF

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EU-EC-	03/03/3033	Spontaneous	Nan		Not	3-11	Not	Female	No	- Other Medically Important Condition) Hypersensitivity (n/a	COMIRNATY	Not vonewheel	TCCD
10011478629	03/02/2022	Sportaneous	Healthcare Professional	European Economic Area	available	Years	Specified		INO	- Recovering/Resolving - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10011479538	03/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	02/02/2022	Canadana	I I a likh a a sa	Non	Note	3-11	Net	Famala	No	Product administered at inappropriate site (n/a - Unknown -)	TOZINAMEDAN	INTUNIV	ICSR
10011479603	03/02/2022	Spontaneous	Professional	Non European Economic Area	Not available	Years	Not Specified	Female	NO	Condition aggravated (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[GUANFACINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral]), [CLOBAZAM] (C - Epilepsy - n/a - [n/a - n/a - Oral]), [LACTOSE] (C - Constipation - n/a - [n/a - n/a - Oral])	
EU-EC- 10011480003	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -), Headache (0d - Unknown -), Pyrexia (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (0d - Recovered/Resolved			
EU-EC- 10011480026	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011480054	03/02/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011480072	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (1d - Recovered/Resolved -), Limb discomfort (1d - Recovered/Resolved -), Vaccination site reaction (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011480095	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	-) Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011480097	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011480315	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pruritus (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]	Not reported	ICSR
EU-EC- 10011480350	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [n/a - n/a - n/a])		
EU-EC- 10011480416	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Headache (2d - Recovered/Resolved -),			
										Injection site inflammation (72h - Recovered/Resolved -),			
										Injection site pain (72h - Recovered/Resolved -),			
										Injection site warmth (72h - Recovered/Resolved -),			
										Malaise (n/a - Recovering/Resolving -),			
										Nausea (2d - Recovered/Resolved -),			
										Pyrexia (n/a - Recovering/Resolving -), Syncope (20s -			
										Recovered/Resolved			
EU-EC- 10011480719	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011480740	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Chills (1d - Not Recovered/Not Resolved -), Headache (2d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -), Malaise (1d - Not Recovered/Not			
EU-EC- 10011480840	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Resolved -) Paraesthesia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011481725	03/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (15h - Recovered/Resolved -), Lethargy (15h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
										Vomiting (15h - Recovered/Resolved			
EU-EC- 10011481734	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011481845	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain upper (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]),	Not reported	ICSR
										Chills (n/a - Recovering/Resolving -),	[AMOXICILLIN] (S - Sinusitis - n/a - [5d - n/a - Oral])		
										Dyspnoea (n/a - Recovering/Resolving -),			
										Hepatic enzyme increased (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011481939	03/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Erythema (10min - Recovered/Resolved -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR	Not reported	ICSR

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										Pruritus (10min - Recovered/Resolved -)	INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - n/a])		
EU-EC- 10011482224	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011482459	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011482505	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011482559	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011482681	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	[Inya - Inya] (S - COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011483171		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Decreased appetite (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Insomnia (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011483341	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011483381	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011483391	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved -), Influenza (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011483398	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011483401	03/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (4d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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EU-EC- 10011483467	03/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Erythema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011483472	03/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Pyrexia (30d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mg - n/a])	Not reported	ICSR
EU-EC- 10011483502	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Eyelid oedema (n/a - Not Recovered/Not Resolved -), Swelling of eyelid (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011483508	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Swelling (1d - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ALKINDI 5 MG [HYDROCORTISONE] (C - Adrenogenital syndrome - n/a - [n/a - n/a - n/a]), [ATOMOXETINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]), [AZITHROMYCIN] (C - Primary ciliary dyskinesia - n/a - [n/a - n/a - n/a]), [FLUDROCORTISONE ACETATE] (C - Adrenogenital syndrome - n/a -	
EU-EC- 10011484925	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Influenza like illness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[n/a - n/a - n/a]) Not reported	ICSR
EU-EC- 10011486088	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Infant	Male	Yes	Aggression (3d - Recovered/Resolved -), Exposure via breast milk (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[DESOGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10011486836	03/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011487360		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Back pain (n/a - Recovering/Resolving -), COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011488097	03/02/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
10011488920		Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Female	Yes	Abdominal pain (15d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (15d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a2mL - Intramuscular])	AVAMYS [FLUTICASONE FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR 22/4

10011462928	02/02/2022	Spontaneous								Important Condition), Pyrexia (1d -		[PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE]	
10011462928 EU-EC- 0	02/02/2022	Spontaneous										HIDROCHLORIDE	
10011462928 EU-EC- 0	02/02/2022	Spontaneous								Recovered/Resolved - Other Medically Important Condition),		(C - n/a - n/a - [n/a - 10mg - n/a])	
10011462928 EU-EC- 0	02/02/2022	Spontaneous								Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
			Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011464159	02/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Product use issue (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011465538	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Caused/Prolonged Hospitalisation) Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
EU-EC- 10011465545)2/02/2022	Spontaneous	Non Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (1d - Recovered/Resolved -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Injection site pain (1d - Recovered/Resolved -),	[1,44 1,44])		
										Myalgia (1d - Unknown -)			
EU-EC- 10011466070	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10011466092	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Rash pruritic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011466098	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSI
EU-EC- 10011466100	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 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])	Not reported	ICSI
EU-EC- 10011466133)2/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Epistaxis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011466252	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Partial seizures (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2ml - n/a])	[SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - n/a])	ICSF
EU-EC- 10011466461	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 03 10011466467	02/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Pain in extremity (1d	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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			Professional	Area						Recovered/Resolved -)	Immunisation - n/a - [n/a - n/a - Subcutaneous])		
EU-EC- 10011466885	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Adult	Female	No	Influenza like illness (27d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10011466914	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Not Recovered/Not Resolved -), Injection site pain (0d - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Vomiting (0d - Unknown -)			
EU-EC- 10011466940	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011467212	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site erythema (3d - Recovered/Resolved -), Injection site inflammation (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
										Injection site pain (3d - Recovered/Resolved -), Injection site swelling (3d - Recovered/Resolved -),			
										Injection site warmth (3d - Recovered/Resolved -)			
EU-EC- 10011467466	02/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011468084	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Pyrexia (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Recovered/Resolved			
EU-EC- 10011468274	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011468286	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011468728	02/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10011468737	02/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Important Condition) COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011468756	02/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	- Other Medically Important Condition) Tardive dyskinesia (n/a - Unknown - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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Peditional Ped	EU-EC- 10011468806	02/02/2022	Spontaneous		European Economic				Male	No	Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
12-12-22-22 Spontamental Name Summer Summer Not Summer	EU-EC- 10011469207	02/02/2022	Spontaneous	Healthcare	European Economic				Male	No	thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
Pealthcase Coronno Pealthcase Coronno Peart Coronno											to patient of inappropriate age (n/a - Unknown - Caused/Prolonged			
## Company Mode Mod	EU-EC- 10011469324	02/02/2022	Spontaneous	Healthcare	Economic			Child	Female	No	(1d - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
BL-EC	EU-EC- 10011469326	02/02/2022	Spontaneous	Healthcare	Economic			Child	Female	No	Injection site pain (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICS
COUNTRATY Not reported CS	EU-EC- 10011469339	02/02/2022	Spontaneous	Healthcare	Economic			Child	Female	No	(1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICS
Recovered/Not Resolved - 1), Pruntus (n/a - Not Recovered/Not Resolved - 2), P	EU-EC- 10011469572	02/02/2022	Spontaneous	Healthcare	Economic			Child	Male	No	Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a	Not reported	ICS
EU-EC. 02/02/2022 Spontaneous Rome Professional Recovered Not Recovering Resolving - (1) -											Recovered/Not Resolved -), Pruritus (n/a - Not			
DEC-0011469970 Part											Resolved -), Urticaria (n/a - Not Recovered/Not			
Diarrhoea (n/a - Not Recovering/Resolving -),	EU-EC- 10011469950	02/02/2022	Spontaneous	Healthcare	Economic				Female	No	Chills (n/a - Recovering/Resolving	[TOZINAMERAN] (S -	Not reported	ICS
D2/02/2022 Spontaneous Non Healthcare Professional Profes				Professional	Area						Diarrhoea (n/a - Recovering/Resolving	immunisation - Not applicable - [n/a -		
Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Vomiting (n/a - Not Recovered/Not Resolved -), Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Recovered/No											Recovered/Not			
Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -) -Not Recovering/Resolving -) -Not Recovering/Resolving -) -Not Recovering/Resolving -) -Not Recovering/											Recovering/Resolving -),			
EU-EC- 102/02/2022 Spontaneous Healthcare Professional P											Recovering/Resolving -),			
EU-EC- 10011469973 Professional Non Healthcare Professional Recovering/Resolving Area Recovering/Resolving Professional Realthcare Professional Resolved -), Healthcare Professional Realthcare Professional Resolved -), Healthcare Professional Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Rec											Recovering/Resolving -),			
EU-EC- 10011469973											Recovering/Resolving -), Vomiting (n/a -			
Professional Area Resolved -), Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),	EU-EC-	02/02/2022	Spontaneous							No	-) Abdominal pain (n/a		Not reported	ICS
Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),	100114699/3					avallable	Years	Specified			Resolved -), Fatigue (n/a - Not Recovered/Not	COVID-19 immunisation - Not applicable - [n/a -		
(n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not											Headache (n/a - Not Recovered/Not			
Recovered/Not											(n/a - Not Recovered/Not			
											Recovered/Not			

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										Nausea (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011469989	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 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	ICSR
EU-EC- 10011470028	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chills (2h - Recovered/Resolved -), Dyspnoea (2h - Recovered/Resolved -), Hyperhidrosis (2h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved -), Malaise (2h - Recovered/Resolved -),			
										Nausea (2h - Recovered/Resolved -),			
										Pallor (2h - Recovered/Resolved -), Vision blurred (2h -			
										Recovered/Resolved			
EU-EC- 10011470070	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 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	ICSR
EU-EC- 10011470095	02/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Not Specified	Male	No	Glossodynia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
			Professional	Area						-), Tongue blistering (n/a - Recovering/Resolving -), Tongue eruption (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10011470151	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pallor (1h - Recovered/Resolved - Other Medically Important Condition), Syncope (3h - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (3h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011470867	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011472244	02/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011473529	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Condition) Injection site pain (1d - Recovering/Resolving		Not reported	ICSR
EU-EC- 10011473897	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	-) Diarrhoea (1d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mg - n/a])	Not reported	ICSR

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EU-EC- 10011473915	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vasculitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011474015	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011474690	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -), Injection site pain (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011474819	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site rash	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011474824	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site lymphadenopathy (4d - Recovered/Resolved -), Vaccination site pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011474837	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Epistaxis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011474877	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011474879	02/02/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Male	No	Circumoral swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011474898	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Axillary pain (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	[AMOXICILLIN] (C - Respiratory tract infection - Drug withdrawn - [8d - 5mL - Oral]), [PARACETAMOL] (C - Pyrexia - Drug withdrawn - [4d - 3mL - Oral])	ICSR
EU-EC- 10011474910	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site lymphadenopathy (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011475077	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Vaccination site lymphadenopathy (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011475084	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (1d - Recovered/Resolved -), Vaccination site pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011475086	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

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										Recovered/Not Resolved -)			
EU-EC- 10011475117	02/02/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	VIth nerve paresis (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011475124	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011475136	02/02/2022	Spontaneous		European Economic Area	Not available	3-11 Years	Child	Female	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011475143	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Pyrexia (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011475430	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Eyelid rash (n/a - Not Recovered/Not Resolved - Disabling), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (n/a - Not Recovered/Not Resolved - Disabling), Rash pruritic (n/a - Not Recovered/Not Resolved - Disabling), Urticaria (n/a - Not Recovered/Not			
EU-EC- 10011475436	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Resolved - Disabling) Chills (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011475911	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Fatigue (2d - Recovered/Resolved -), Rash (5d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475913	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475915	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (4d - Recovered/Resolved -), Lymphadenopathy (17d - Not Recovered/Not Resolved -), Malaise (15d - Recovering/Resolving -), Sleep disorder (15d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (3d - Recovered/Resolved -)			
EU-EC- 10011475920	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Resolved -),			
										Vomiting (1d - Recovered/Resolved -)			
EU-EC- 10011475921	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475923	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (0d - Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10011475925	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (1d - Recovered/Resolved -), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Injection site pain			
										(2d - Recovered/Resolved -)			
EU-EC- 10011475928	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (13d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475929	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (4d - Not Recovered/Not Resolved -), Urticaria (4d - Not			
EU-EC-	02/02/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Recovered/Not Resolved -)	COMIRNATY	Not reported	ICSR
10011475931		'	Healthcare	Economic Area	available	Years				Recovered/Resolved -), Nausea (1d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
										Recovered/Resolved -), Vomiting (1d -			
EU-EC- 10011475937	02/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Male	No	Recovered/Resolved -) Headache (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
10011 1/3337				Area	available	rears				-), Malaise (3d - Recovered/Resolved	Immunisation - n/a - [n/a - n/a - n/a])		
										-), Rash (2d - Recovered/Resolved			
EU-EC- 10011475944	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (5d - Recovering/Resolving		Not reported	ICSR
EU-EC- 10011475947	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (n/a - Unknown -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Injection site pain (n/a - Not Recovered/Not Resolved -),	[n/a - n/a - n/a])		
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011475948	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475955	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site erythema (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (1d - Recovered/Resolved			
										Injection site swelling (1d - Recovered/Resolved			
										-),			

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										Rash (0d - Recovered/Resolved -), Vaccination site reaction (1d -			
										Recovered/Resolved			
EU-EC- 10011475959	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475961	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (1d - Recovered/Resolved -), Injection site pain (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10011475974	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved -), Rash vesicular (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	02/02/2022	Cantonoous	Non	Furancan	Not	2 11	Child	Famala	No	Not Recovered/Not Resolved -)	COMIDNATY	Not reported	TCCD
10011475975	02/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (21d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (n/a - Recovered/Resolved -),			
										Lymphadenopathy (21d - Recovered/Resolved			
EU-EC- 10011475977	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Pyrexia (1d - Not Recovered/Not Resolved -),	[n/a - n/a - n/a])		
										Swelling of eyelid (1d - Not Recovered/Not Resolved -)			
EU-EC- 10011475981	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475982	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthritis (4d - Recovered/Resolved -), Limb discomfort (4d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										- Recovered/Resolved -)			
EU-EC- 10011475991	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011475998	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Limb discomfort (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Oedema peripheral (1d - Recovering/Resolving	[iva iva iva])		
										Pruritus (7d - Not Recovered/Not Resolved -),			
										Rash (7d - Not Recovered/Not Resolved -),			
										Urticaria (7d - Not Recovered/Not Resolved -)			
EU-EC- 10011476002	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Influenza (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pain in extremity (2d - Recovered/Resolved -)	, -aa1/		
EU-EC- 10011476003	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Influenza like illness (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR

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										Vomiting (2d - Recovered/Resolved			
EU-EC- 10011476008	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Influenza like illness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Vaccination site reaction (0d - Recovered/Resolved -)			
EU-EC- 10011476009	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site swelling (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011476010	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011476015	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Influenza (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011476019	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (7d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Myalgia (7d - Recovered/Resolved -)			
EU-EC- 10011476033	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Diplopia (0d - Unknown -), Dizziness (4d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown -), Rash (3d - Recovered/Resolved			
										Urticaria (3d - Recovered/Resolved			
EU-EC- 10011476037	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Lymphadenopathy (17d - Not Recovered/Not Resolved -),	[n/a - n/a - n/a])		
										Malaise (15d - Recovering/Resolving -),			
										Vomiting (3d - Recovered/Resolved -)			
EU-EC- 10011476041	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain lower (17d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Fatigue (17d - Not Recovered/Not Resolved -),	Intramuscular])		
										Headache (17d - Not Recovered/Not Resolved -),			
										Nausea (17d - Not Recovered/Not Resolved -)			
EU-EC- 10011476042	02/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011476044	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pruritus (7d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rash (7d - Not Recovered/Not Resolved -),			
										Urticaria (7d - Not Recovered/Not Resolved -)			

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EU-EC- 10011476046	02/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Neuralgia (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011449063	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Resolved -) Migraine (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011449297	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Injection site swelling (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011449536	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Urticaria (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011449609	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Injection site pain (7d - Recovered/Resolved -), Lymphadenopathy (7d - Recovered/Resolved -), Pyrexia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011449614	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Flushing (n/a - Not Recovered/Not Resolved -), Skin warm (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011450009	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Resolved -) Vascular purpura (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011450288	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011450877	01/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011452294	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Lethargy (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pruritus (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Skin reaction (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR

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EU-EC- 10011452461	01/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011452769	01/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011452770	01/02/2022	Spontaneous		Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011455194	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Illusion (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown -), Vertigo (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011455524	01/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Muscle spasms (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011455630	01/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Important Condition) Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Presyncope (n/a - Recovered/Resolved -)			
EU-EC- 10011455704	01/02/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a	Not reported	ICSR
										Cough (n/a - Unknown -), Drug ineffective (n/a	- n/a])		
										- Unknown - Other Medically Important Condition),			
EU-EC- 10011456417	01/02/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Headache (n/a - Unknown -) Injection site pain (2d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
EU-EC- 10011456535	01/02/2022	Spontaneous		Area European Economic	Not available	3-11 Years	Child	Female	No	Recovered/Resolved -) Chills (1d - Recovered/Resolved	Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
				Area	2.3.1000	. 34.3				-), Dizziness (1d - Unknown -),	Immunisation - n/a - [n/a - n/a - n/a])		

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										Injection site pain (3d - Unknown -),			
										Tachycardia (2d - Recovered/Resolved -)			
EU-EC- 10011456556	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011456589	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011456591	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011457307	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site pain (3d - Recovered/Resolved -), Myalgia (2d -	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011457348	01/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Recovered/Resolved -) Influenza (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR
1001173/370				Area	avallable	leais				Injection site pain (2d - Recovered/Resolved	Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10011457350	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011459119	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -), Malaise (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Myalgia (n/a - Unknown -), Vaccination site joint movement impairment (n/a - Unknown -),	·		
										Vaccination site pain (n/a - Unknown -)			
EU-EC- 10011460547	01/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Overdose (n/a - Unknown -), Product preparation error (n/a - Unknown	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
EU-EC- 10011461246	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011461250	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dyspnoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011461251	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011461255	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Injection site hypersensitivity (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- 10011461263	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011461351	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Dysphagia (3d - Recovered/Resolved - Other Medically Important Condition), Vaccination site inflammation (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d1mL - Intramuscular])	Not reported	ICSR

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EU 50	04 (02 (2022			_		2.44	0.7.1			Important Condition)	COMPAND		1.000
EU-EC- 10011461483	01/02/2022	Spontaneous	Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Myelitis transverse (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICS</u>
EU-EC- 10011461577	01/02/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown -), Generalised tonic- clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
										Vomiting (n/a - Unknown -)			
EU-EC- 10011461709	01/02/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Arthralgia (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular])	Not reported	ICSR
										Condition), Herpes zoster (n/a - Unknown - Other Medically Important Condition),			
										Oral herpes (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Skin papilloma (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site lymphadenopathy (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011462477	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (0d - Recovered/Resolved -), Menstrual disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011462478	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Abdominal pain (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011462488	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual discomfort (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462489		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	- Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462492		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Oral herpes (109d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462496		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthritis (19d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462501		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Proteinuria (3d - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011462502		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011462503		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	01/02/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Menstrual disorder	COMIRNATY	Not reported	ICSR

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10011462506			Healthcare Professional	Economic Area	available	Years				(1d - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011462508	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Injection site pain	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										(2d - Recovered/Resolved			
EU-EC- 10011462510	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462511	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Eye swelling (1d - Recovering/Resolving -), Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pruritus (1d - Recovering/Resolving -)			
EU-EC- 10011462512	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Hypersensitivity (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Lacrimation increased (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011462513	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462514	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Chest pain (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cyanosis (1d - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Malaise (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011462515	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462517	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	No adverse event (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462525	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Diarrhoea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462526	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Epistaxis (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462527	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Epilepsy (0d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462529	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Epistaxis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462530	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Aphthous ulcer (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462542	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (1d - Unknown -), Headache (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (1d - Recovered/Resolved -)			

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EU-EC- 10011462544	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual discomfort (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462545	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Loss of consciousness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462547	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Oral mucosal blistering (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462548		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Abdominal pain (0d - Recovered/Resolved -), Dizziness (0d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Malaise (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462550	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Muscle twitching (13d - Recovered/Resolved -), Paraesthesia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462554	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Menstrual disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462557	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Infectious mononucleosis (17d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462559	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Epididymitis (9d - Recovered/Resolved -), Sinusitis (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462562	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Injection site pain (0d - Recovered/Resolved -), Nipple pain (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011462655	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011462721	01/02/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Fatigue (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Injection site pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011462726	01/02/2022	Spontaneous	Non Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Epilepsy (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

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EU-EC-	01/02/2022	Spontaneous	Non	Europoan	Not	3-11	Child	Female	No	Hospitalisation) Haematoma (4d -	[n/a - n/a - n/a]) COMIRNATY	Not reported	ICS
10011462729	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	available	Years	Child	гетта	INO	Recovered/Resolved - Caused/Prolonged Hospitalisation), Henoch-Schonlein	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	103
										purpura (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Rash (4d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011462740	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
EU-EC-	01/02/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) Arrhythmia (10d -	COMIRNATY	Not reported	ICSF
10011462747	01/02/2022	Spontaneous	Healthcare Professional	Economic Area	available	Years	Ciliu	remaie	No	Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	100
										Chest discomfort (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Somnolence (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011462758	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Gastrointestinal pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Nausea (1d - Recovered/Resolved -)			
EU-EC- 10011462768	01/02/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (2d - Recovering/Resolving -), Language disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										(2d - Recovering/Resolving -)			
EU-EC- 10011437176	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Faeces soft (4d - Recovered/Resolved -), Fatigue (4d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 10uq -	Not reported	ICSI
										-), Injection site pain (4d - Recovered/Resolved	Intramuscular])		
EU-EC- 10011437267	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Diarrhoea (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Headache (2d - Recovered/Resolved -), Pyrexia (1d -			
EU EC	21/01/2022	Cnorter	Non	Eugene	Not	2 11	Child	For-s'-	Ne	Recovering/Resolving -)	COMIDNATY	Not roperted	Too
EU-EC- 10011437269		Spontaneous Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female Male	No No	Restlessness (2d - Recovered/Resolved -) Body temperature	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY	Not reported Not reported	ICSR ICSR
10011437282	31/01/2022	Spontaneous				Years	Cilliu	inale	INO	abnormal (0d -	[TOZINAMERAN] (S -	not reported	1038

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			Professional	Area						Recovered/Resolved -),	Immunisation - n/a - [n/a - n/a - n/a])		
										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10011437286	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Arthralgia (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Injection site pain (33d - Recovered/Resolved	[n/a - n/a - n/a])		
FIL 50	24 (04 (2022	6	N	F	NI-1	2.44	Child	24.1	N1 .	-)	COMPRIATO	Niel er de d	TOOD
EU-EC- 10011437295	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Dizziness (5d - Unknown -), Feeling cold (5d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Headache (3d - Recovering/Resolving -),			
										Injection site erythema (3d - Recovering/Resolving -),			
										Injection site pain			
										(5d - Recovering/Resolving -),			
										Injection site swelling (3d - Recovering/Resolving -),			
										Malaise (1d - Recovering/Resolving -)			
EU-EC- 10011437304	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011437311	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011437313	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011437326	31/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Female	No	Gastrointestinal pain (6d - Unknown -), Menarche (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011437331	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Herpes simplex (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
EU-EC- 10011437332	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (1d - Recovering/Resolving -),	[n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSR
										Chills (1d - Recovered/Resolved -),	[n/a - n/a - n/a])		
										Fatigue (1d - Recovering/Resolving -),			
										Headache (1d - Recovered/Resolved -),			
										Injection site pain (1d - Recovered/Resolved			
										-), Pyrexia (1d - Recovering/Resolving			
EU-EC-	31/01/2022	Spontaneous	Non	European	Not	3-11	Child	Male	No	-) Disturbance in	COMIRNATY	Not reported	ICSR
10011437335		·	Healthcare Professional	Economic Area	available	Years				attention (3d - Recovered/Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011437342	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Alopecia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011437346	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Enuresis (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	31/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Rash (n/a - Not	COMIRNATY	Not reported	ICSR

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10011437349			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011437637	31/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC- 10011438377	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Important Condition) Body temperature increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011438400	31/01/2022	Spontaneous	Healthcare	European Economic	Not available	3-11 Years	Child	Female	No	Vomiting (n/a - Not Recovered/Not Resolved -) Axillary pain (n/a - Not Recovered/Not	19 MRNA VACCINE	Not reported	ICSR
			Professional	Area						Resolved -), Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -)	(NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION 10 MICROGRAMS/DOSE [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10011438443	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Hypokinesia (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Resolved -),	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION 10 MICROGRAMS/DOSE [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Vaccination site warmth (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011438796	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Conjunctival hyperaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hand-foot-and-mouth disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Unknown - Unknown - Unknown - Unknown - Unknown -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral])	

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EU-EC- 10011439540	31/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (n/a - Recovered/Resolved -)			
EU-EC- 10011439671	31/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Product administered to patient of inappropriate age (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011439685	31/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011439687	31/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011440199	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	-) Dermatitis allergic (n/a - Recovered/Resolved -), Eye allergy (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011440460	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	-) Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (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- 10011440473	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011441767	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Vaccination site reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011441957	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Lymph node pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Lymphadenopathy (n/a - Unknown - Other Medically Important Condition),			
										Pharyngitis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a -			
EU-EC-	31/01/2022	Spontaneous	Non	European	Not	3-11	Child	Female	No	Unknown - Other Medically Important Condition)	COMIRNATY	Not reported	ICSR
10011442075	_, - =, = ====		Healthcare Professional	Economic Area	available	Years				(n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		

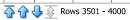
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										-),			
										Throat irritation (n/a			
										Recovering/Resolving			
EU-EC- 10011442128	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Cold sweat (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
	24 (04 (2222									-), Nausea (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011442156	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cough (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Rhinitis (n/a - Recovering/Resolving -), Viral infection (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011442236	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Abdominal pain (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Feeling cold (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011442269		Spontaneous	Healthcare Professional		Not available	3-11 Years	Child	Male	No	Gastrointestinal disorder (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pollakiuria (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vaccination site paraesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011442313	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Asthenia (n/a - Recovering/Resolving -), Asthma (n/a - Recovering/Resolving -), Cough (n/a - Recovering/Resolving -), Feeding disorder (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Taste disorder (n/a - Recovering/Resolving -), Taste disorder (n/a - Recovering/Resolving -),		KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - n/a - Oral]), [FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [OMEPRAZOLE, OMEPRAZOLE, OMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a - Oral]), [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-	31/01/2022	Spontaneous		European	Not	3-11	Child	Male	No	-) Rash (0d -	COMIRNATY	Not reported	ICSR
10011442400			Healthcare	Economic	available	Years				Recovered/Resolved	[TOZINAMERAN] (S -		

								\\			1		
			Professional	Area						-)	Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011442587	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .2mL - Intramuscular])	Not reported	ICSI
EU-EC- 10011442958	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSF
10011443318	31/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Recovered/Not Resolved -) Disorientation (0d - Recovered/Resolved -), Dizziness (0d - Recovered/Resolved -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Ocular hyperaemia (n/a - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Unknown]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSF
EU-EC- 10011443368	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011443910	31/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Pallor (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011444019	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Headache (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011444023	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011444119	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Headache (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011444177	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Diarrhoea (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mg - n/a])	Not reported	ICSR
EU-EC- 10011444703	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Presyncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Recovering/Resolving			
EU-EC- 10011445416	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	-) Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011445421	31/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site pain (1d - Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011446968		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	-) Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Pyrexia (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- 10011448127	31/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	3-11 Years	Child	Female	No	Anaphylactic reaction (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 10ug - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011448169	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Autoimmune haemolytic anaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011448184	31/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011448243	31/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011430284	30/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

J.11.2022 U									, EI3(III) 	Other Medically			
EU-EC-	20/01/2022	Spontaneous	Non	Non	Not	3-11	Not	Male	No	Important Condition)	TOZINAMERAN	Not reported	ICS
10011430286	30/01/2022	spontaneous	Healthcare Professional	Non European Economic Area	available	Years	Specified	мане	NO	Anaphylactic reaction (6620min - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pharyngeal swelling	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	100
										(n/a - Unknown - Caused/Prolonged Hospitalisation), Swelling face (n/a -			
										Unknown - Caused/Prolonged Hospitalisation), Swollen tongue (n/a			
EU-EC-	30/01/2022	Spontaneous	Healthcare	European	Not	3-11	Not	Male	No	- Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY	Not reported	ICS
10011430940	30/01/2022	Spontaneous	Professional	Economic Area	available	Years	Specified	Мане	NO	Unknown -), Hypothermia (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Not applicable - [1d - 10ug - n/a])	Not reported	103
EU-EC- 10011430990	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	I (UI) - II/a])		
EU-EC- 10011430991	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10011431430	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Rash (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011431544	30/01/2022	Spontaneous	Non Healthcare Professional		Not available	3-11 Years	Child	Male	No	Injection site pain (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10011431570	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011431627	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Cough (1d - Recovering/Resolving -), Dizziness (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Recovered/Resolved -), Headache (3d -			
										Recovering/Resolving -), Influenza (2d - Recovering/Resolving			
										Injection site pain			
										Recovered/Resolved -), Pyrexia (2d - Recovering/Resolving			
EU-EC- 10011431667	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Chills (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSI
										Fatigue (0d - Recovered/Resolved -)	[n/a - n/a - n/a])		
EU-EC- 10011431674	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	No adverse event (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a -	Not reported	ICSI

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EU-EC- 10011431684	30/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Male	No	No adverse event (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011431697		Spontaneous	Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Fatigue (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Injection site swelling (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011431700	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011431724	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Fatigue (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site pain (0d - Recovered/Resolved -), Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011431738	30/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	3-11 Years	Child	Male	No	Fatigue (1d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR



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