

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-10007407097	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10007411955	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007412568	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Conjunctivitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - .3mL - Intramuscular])	[BISOPROLOL FUMARATE] (C - Hypertension - n/a - [n/a - 2{DF} - Oral]), [INDAPAMIDE, AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - Hypertension - n/a - [n/a - 1{DF} - Oral])	ICSR
EU-EC-10007413079	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Conjunctivitis (n/a - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	[RABEPRAZOLE, RABEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 10mg - Oral]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-10007392059	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007392356	21/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Disease recurrence (12d - Recovered/Resolved - Other Medically Important Condition), Ear pain (12d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (12d - Recovered/Resolved - Other Medically Important Condition), Facial paresis (12d - Recovered/Resolved - Other Medically Important Condition), Headache (12d - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (12d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RELVAR ELLIPTA [FLUTICASON FUROATE, VILANTEROL] (C - Asthma - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a]), [INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10007392525	21/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Allergy to vaccine (n/a - Recovered/Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved -), Paraesthesia oral (n/a - Recovered/Resolved -), Rash erythematous (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007393097	21/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paralysis (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-10007393151	21/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cerebellar infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paralysis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007393844	21/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007393853	21/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR

										Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10007395628	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cheilitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dry eye (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lacrimation decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle twitching (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Swelling face (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-10007400623	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007385209	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (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-10007389602	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (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-10007371706	19/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Disabling, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a - n/a -	ICSR

	Area	Important Condition),	immunisation - Not applicable - [1d - n/a - n/a]	n/a), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Carpal tunnel syndrome - n/a - [n/a - n/a - n/a])
		Balance disorder (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Confusional state (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Costochondritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),		
		Diplopia (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),		
		Dizziness (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Dysarthria (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),		
		Erythema (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Eye pain (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),		
		Facial pain (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Facial paralysis (2d - Recovering/Resolving - Disabling, Other Medically Important Condition),		
		Fatigue (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Hypoaesthesia (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Lacrimation increased (n/a - Unknown - Disabling, Other Medically Important Condition),		
		Lymphadenopathy (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),		
		Middle ear inflammation (4d - Recovered/Resolved - Disabling, Other Medically Important Condition),		
		Migraine with aura (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),		

										<p>Nausea (4d - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Oropharyngeal pain (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Pain (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Rales (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Somnolence (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Swelling face (2d - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition)</p>			
EU-EC-10007373262	19/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Ear pain (n/a - Recovering/Resolving -),</p> <p>Eye pain (n/a - Recovering/Resolving -),</p> <p>Facial pain (n/a - Recovering/Resolving -),</p> <p>Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Hypoaesthesia (n/a - Recovering/Resolving -),</p> <p>Pain in jaw (n/a - Recovering/Resolving -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007373381	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	<p>Eyelid function disorder (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Facial paresis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Headache (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Paraesthesia oral (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Skin burning sensation (n/a - Recovering/Resolving - Other Medically Important Condition)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL ARGININE] (C - Hypertension - Unknown - [n/a - n/a - Oral])	ICSR
EU-EC-10007376034	19/01/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Area						Medically Important Condition)	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC-10007377192	19/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[TAMOXIFEN CITRATE] (C - Breast cancer female - n/a - [n/a - 20mg - Oral])	ICSR
EU-EC-10007377217	19/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paralysis (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-10007378243	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Not Specified	No	Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007378650	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007378942	19/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial pain (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -), Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pain in jaw (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (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
EU-EC-	18/01/2021	Spontaneous	Healthcare	Non	Not	65-85	Not	Female	No	Facial paralysis (n/a -	TOZINAMERAN	Not reported	

10007363518			Professional	European Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])		ICSR
EU-EC-10007363521	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007363599	18/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Paraesthesia oral (n/a - Not Recovered/Not Resolved -), Vaccination site paraesthesia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[IBUPROFEN, NAPROXEN, NAPROXEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007363726	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007364003	18/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007364795	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007366773	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Blepharospasm (n/a - Not Recovered/Not Resolved - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10007367567	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007369324	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007369329	18/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Recovered/Resolved -), Periorbital swelling (n/a - Unknown -), Pruritus (n/a - Unknown -), Rash (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Swelling face (n/a - Unknown -), Swelling of eyelid (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)			
EU-EC-10007369346	18/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007369358	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ageusia (n/a - Unknown -), Eye movement disorder (n/a - Unknown -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007369362	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007369441	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Eye pruritus (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10007369450	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Eye disorder (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Occipital neuralgia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007363018	17/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (2h - 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-10007363161	17/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007354457	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ETANERCEPT [ETANERCEPT] (C - Psoriatic arthropathy - n/a - [n/a - n/a - Subcutaneous]), METHOTREXATE [METHOTREXATE] (C - Psoriatic arthropathy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007355043	15/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Diarrhoea (1h - Recovered/Resolved - Other Medically Important Condition), Dysarthria (1h - Recovered/Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	[SIMVASTATIN] (C - Blood cholesterol - n/a - [n/a - n/a - n/a])	ICSR

										Facial paralysis (1h - Recovered/Resolved - Other Medically Important Condition), Unresponsive to stimuli (1h - Recovered/Resolved - Other Medically Important Condition), Vomiting (1h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007356796	15/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (2d - Recovered/Resolved - Other Medically Important Condition), Fatigue (16d - Recovered/Resolved - Other Medically Important Condition), Headache (7d - Recovered/Resolved - Other Medically Important Condition), Injection site pain (5d - Recovered/Resolved -), Myalgia (13d - Recovered/Resolved - Other Medically Important Condition), Nausea (9d - Recovered/Resolved - Other Medically Important Condition), Palpitations (13d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved -), Sensory disturbance (n/a - Unknown -), Spinal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site erythema (7d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (5d - Recovered/Resolved - Other Medically Important Condition), Vaccination site swelling (16d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007360283	15/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial pain (n/a - Not Recovered/Not Resolved - Disabling), Facial paralysis (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Not Recovered/Not Resolved - Disabling), Noninfective encephalitis (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC-10007346801	14/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007348199	14/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Myalgia (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007349916	14/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - .3mL - Intramuscular])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007351373	14/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Female	No	Back pain (n/a - Recovering/Resolving -), Chest discomfort (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Ear pain (n/a - Recovering/Resolving -), Facial pain (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paresis (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -), Paraesthesia (n/a - Recovering/Resolving -), Peripheral coldness (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[BIOTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MESALAZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MINERALS NOS, VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10007352598	14/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Blood pressure systolic increased (n/a - Unknown -), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Otitis media (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Dyspepsia - n/a - [n/a - 40mg - n/a])	ICSR
EU-EC-10007352940	14/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Dysarthria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007353493	14/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [3d - 1{DF} - Unknown])	NOT AVAILABLE (C - n/a - n/a -), REVELA 2.4 G POWDER FOR ORAL SUSPENSION [SEVELAMER CARBONATE] (C - n/a - n/a -), VELPHORO 500 MG CHEWABLE TABLETS [IRON, SUCROFERRIC OXYHYDROXIDE] (C - n/a - n/a -), [ATORVASTATIN, EZETIMIBE] (C - n/a - n/a -), [BETAHISTINE DIHYDROCHLORIDE] (C - n/a - n/a -), [BISOPROLOL FUMARATE] (C - n/a - n/a -), [CALCIFEDIOL] (C - n/a - n/a -), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a -), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - n/a -), [FUROSEMIDE] (C - n/a - n/a -), [PARICALCITOL] (C - n/a - n/a -)	ICSR
EU-EC-10007353672	14/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Herpes zoster oticus (n/a - Unknown - Other Medically Important Condition), Rash vesicular (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-10007341040	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007341517	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - Immunisation - n/a - [n/a - n/a - n/a]), [LOSARTAN POTASSIUM] (C - Hypertension - n/a -)	ICSR


										Resolved - Other Medically Important Condition)		[n/a - n/a - n/a]	
EU-EC-10007341974	13/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Facial paralysis (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007344586	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[OMEPRAZOLE] (C - Reflux gastritis - n/a - [n/a - 20mg - n/a])	ICSR
EU-EC-10007344854	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Influenza like illness (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	ICSR
EU-EC-10007345051	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Blood pressure increased (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia oral (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Paraesthesia oral (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10007347464	13/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a]), [ATORVASTATIN CALCIUM] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiac disorder - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 20mg - n/a])	ICSR
EU-EC-10007347593	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007347668	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved -), Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown -), Neck pain (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Sensory disturbance (n/a - Unknown -), Swelling face (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Unknown -)			
EU-EC-10007333321	12/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007337048	12/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Influenza like illness (2wk - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007339585	12/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Lacrimation increased (n/a - Not Recovered/Not Resolved - Disabling), Vision blurred (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BYDUREON [EXENATIDE] (C - n/a - n/a - [n/a - 2mg - Subcutaneous]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 12.5mg - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 40mg - n/a]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [PNEUMOCOCCAL VACCINE] (C - n/a - n/a - [1d - n/a - n/a]), [TETANUS VACCINES] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10007325325	11/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Stress (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007325366	11/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007325577	11/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Facial paralysis (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-10007325813	11/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (3d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 30mg - Oral])	ICSR

										-), Pain (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Paraesthesia (5d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia oral (5d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007326689	11/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - n/a - n/a - [n/a - 4mg - n/a]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - 500mg - n/a]), [BUTALBITAL, PARACETAMOL, CAFFEINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, VITAMIN B12] (C - n/a - n/a - [n/a - 500mg - n/a]), [DICLOFENAC, DICLOFENAC DIETHYLAMINE, DICLOFENAC EPOLAMINE, DICLOFENAC POTASSIUM, DICLOFENAC RESINATE, DICLOFENAC SODIUM, DICLOFENAC SODIUM PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 200ug - n/a]), [LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 25mg - n/a]), [VALSARTAN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007329351	11/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007331645	11/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007318355	08/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (45min - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (45min - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007318826	08/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (1d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007319816	08/01/2021	Spontaneous	Non Healthcare	Non European	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a -)	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR

			Professional	Economic Area						Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-10007322605	08/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007314300	07/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dry eye (n/a - Unknown -), Ear disorder (n/a - Unknown -), Ear pain (n/a - Not Recovered/Not Resolved -), Eye irritation (n/a - Unknown -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia oral (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Unknown -), Wrong technique in product usage process (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Urticaria - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10007304749	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eye pain (n/a - Unknown -), Eyelid ptosis (n/a - Unknown - Other Medically Important Condition), Facial pain (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Swelling face (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007304759	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ear pruritus (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Vaccination site paraesthesia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDRALAZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007306001	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (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-10007307263	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[OLMESARTAN MEDOXOMIL] (C - n/a - n/a - [n/a - n/a - n/a]), [VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007308102	06/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Myocardial infarction	TOZINAMERAN [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										(n/a - Unknown - Other Medically Important Condition)			
EU-EC-10007309958	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ear discomfort (n/a - Recovering/Resolving -), Eye disorder (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoesthesia (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007297498	05/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eyelid disorder (0d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (0d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007292819	04/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in jaw (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007296117	04/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR


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