

Summary Tabulation 29.06.2021

Active Substance (High Level)		COVID-19 MRNA VACCINE MODERNA (CX-024414)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	2	1	3
	Lymph node pain	0	1	1
	Lymphadenitis	1	0	1
	Lymphadenopathy	8	1	9
	Thrombocytopenia	3	0	3
Cardiac disorders	Arrhythmia	1	0	1
	Atrial fibrillation	2	0	2
	Bradycardia	1	0	1
	Cardiac arrest	2	0	2
	Cardiac failure	2	0	2
	Cardiovascular disorder	15	2	17
	Coronary artery occlusion	1	0	1
	Extrasystoles	1	0	1
	Palpitations	6	2	8
	Pericarditis	2	1	3
	Tachycardia	5	3	8
Ear and labyrinth disorders	Deafness	1	0	1
	Ear discomfort	1	0	1
	Ear pain	1	0	1
	Hyperacusis	2	0	2
	Tinnitus	7	0	7
	Vertigo	4	1	5
Endocrine disorders	Goitre	1	0	1
	Hypothyroidism	1	0	1
Eye disorders	Conjunctival haemorrhage	1	0	1
	Diplopia	0	1	1
	Eye oedema	0	1	1
	Eye pain	2	0	2
	Iridocyclitis	0	1	1
	Lacrimation increased	0	1	1
	Photophobia	1	0	1
	Scleritis	1	0	1
	Swelling of eyelid	0	1	1
	Uveitis	0	1	1
	Vision blurred	2	0	2

	Visual impairment	2	1	3
Gastrointestinal disorders	Abdominal discomfort	0	1	1
	Abdominal pain	7	2	9
	Abdominal pain upper	2	1	3
	Aphthous ulcer	1	0	1
	Diarrhoea	11	5	16
	Dyspepsia	1	0	1
	Haematochezia	1	0	1
	Hypoaesthesia oral	0	1	1
	Lip swelling	3	1	4
	Nausea	126	26	152
	Paraesthesia oral	1	1	2
	Retching	0	1	1
	Swollen tongue	2	0	2
	Vomiting	22	5	27
General disorders and administration site conditions	Adverse reaction	0	1	1
	Asthenia	13	4	17
	Axillary pain	0	5	5
	Chest discomfort	2	2	4
	Chest pain	4	2	6
	Chills	195	38	233
	Cyst	0	1	1
	Death	6	0	6
	Discomfort	2	0	2
	Extensive swelling of vaccinated limb	40	7	47
	Face oedema	0	1	1
	Fatigue	227	47	274
	Feeling abnormal	1	1	2
	Feeling cold	2	1	3
	Feeling hot	5	1	6
	Feeling of body temperature change	3	0	3
	Gait disturbance	3	0	3
	General physical health deterioration	1	0	1
	Hyperthermia	0	1	1
	Hypothermia	1	0	1
	Illness	1	0	1
	Inflammation	1	0	1
	Inflammatory pain	1	0	1
	Influenza like illness	28	4	32
	Injected limb mobility decreased	1	0	1
	Injection site bruising	1	0	1
	Injection site erythema	6	13	19
	Injection site haematoma	2	0	2
	Injection site hypersensitivity	0	1	1
	Injection site induration	2	5	7
	Injection site movement impairment	1	0	1
	Injection site oedema	1	0	1
Injection site pain	14	12	26	
Injection site paraesthesia	1	0	1	
Injection site pruritus	0	3	3	

	Injection site reaction	170	34	204
	Injection site swelling	5	5	10
	Injection site warmth	1	0	1
	Malaise	128	28	156
	Mass	0	1	1
	Oedema peripheral	1	0	1
	Pain	5	3	8
	Peripheral swelling	17	6	23
	Pyrexia	243	52	295
	Sudden death	1	0	1
	Swelling face	2	1	3
	Terminal state	1	0	1
	Vaccination failure	1	0	1
	Vaccination site erythema	2	1	3
	Vaccination site lymphadenopathy	0	1	1
	Vaccination site mass	1	1	2
	Vaccination site movement impairment	2	0	2
	Vaccination site pain	4	1	5
	Vaccination site swelling	3	0	3
Hepatobiliary disorders	Liver disorder	1	0	1
Immune system disorders	Allergy to vaccine	1	0	1
	Anaphylactic reaction	4	0	4
	Anaphylactic shock	1	0	1
	Autoimmune disorder	0	1	1
	Hypersensitivity	5	1	6
	Immune system disorder	0	1	1
Infections and infestations	COVID-19	15	0	15
	COVID-19 pneumonia	1	0	1
	Cellulitis	1	0	1
	Erysipelas	1	0	1
	Herpes zoster	4	11	15
	Influenza	2	0	2
	Nasopharyngitis	1	0	1
	Peritonsillar abscess	1	0	1
	Pneumonia	2	0	2
	Vaccination site joint infection	1	0	1
Injury, poisoning and procedural complications	Airway burns	1	0	1
	Cartilage injury	1	0	1
	Contusion	0	3	3
	Exposure via breast milk	1	0	1
	Fall	1	1	2
	Inappropriate schedule of product administration	0	1	1
	Off label use	0	1	1
	Product dose omission issue	2	0	2
	Investigations	Blood pressure decreased	2	0
Body temperature abnormal		1	0	1
Body temperature increased		1	1	2
C-reactive protein increased		0	1	1
Fibrin D dimer increased		1	0	1
Heart rate increased		3	1	4

	Heart rate irregular	0	1	1
	Liver function test abnormal	1	0	1
	Oxygen saturation decreased	3	1	4
	Platelet count decreased	1	0	1
	Red blood cell count decreased	1	0	1
	Weight increased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	15	1	16
Musculoskeletal and connective tissue disorders	Arthralgia	131	17	148
	Back pain	1	2	3
	Joint swelling	1	1	2
	Limb discomfort	4	1	5
	Muscle rigidity	2	0	2
	Muscle spasms	0	1	1
	Muscular weakness	6	1	7
	Musculoskeletal discomfort	1	0	1
	Musculoskeletal stiffness	4	2	6
	Myalgia	208	54	262
	Neck pain	2	2	4
	Pain in extremity	12	13	25
	Pain in jaw	1	0	1
	Polymyalgia rheumatica	0	1	1
Nervous system disorders	Ageusia	2	1	3
	Altered state of consciousness	1	0	1
	Anosmia	1	0	1
	Balance disorder	3	0	3
	Bell's palsy	0	1	1
	Burning sensation	0	3	3
	Cerebral artery thrombosis	1	0	1
	Cerebral thrombosis	1	0	1
	Cerebrovascular accident	3	1	4
	Dizziness	24	4	28
	Dysarthria	1	0	1
	Dysgeusia	2	0	2
	Dystonia	1	0	1
	Facial paralysis	1	4	5
	Haemorrhagic transformation stroke	1	0	1
	Head discomfort	2	0	2
	Headache	207	46	253
	Hemianopia	0	1	1
	Hyperaesthesia	1	1	2
	Hypoaesthesia	4	2	6
	Hypokinesia	1	0	1
	Hyporeflexia	1	0	1
	Ischaemic stroke	1	0	1
	Loss of consciousness	2	1	3
	Migraine	6	1	7
	Nervous system disorder	5	2	7
	Neuralgia	1	0	1
	Paraesthesia	2	2	4

	Paralysis	1	0	1
	Paraplegia	1	0	1
	Paresis	1	0	1
	Parosmia	1	0	1
	Post herpetic neuralgia	0	1	1
	Presyncope	1	2	3
	Retinal migraine	0	1	1
	Seizure	0	1	1
	Sensorimotor disorder	1	0	1
	Sleep deficit	2	0	2
	Somnolence	3	0	3
	Spinal artery embolism	1	0	1
	Syncope	5	3	8
	Taste disorder	2	0	2
	Tension headache	0	1	1
	Transient ischaemic attack	1	0	1
	Tremor	1	0	1
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	1
Psychiatric disorders	Abnormal dreams	1	0	1
	Apathy	1	0	1
	Confusional state	0	1	1
	Insomnia	3	0	3
	Restlessness	1	0	1
Renal and urinary disorders	Chromaturia	1	0	1
	Polyuria	1	0	1
	Renal disorder	1	0	1
	Strangury	1	0	1
Reproductive system and breast disorders	Breast engorgement	1	0	1
	Breast mass	1	0	1
	Breast pain	2	0	2
	Breast swelling	1	0	1
	Heavy menstrual bleeding	0	3	3
	Intermenstrual bleeding	0	1	1
	Menstrual disorder	1	1	2
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Apnoea	1	0	1
	Asphyxia	1	0	1
	Choking sensation	0	2	2
	Cough	5	2	7
	Dysphonia	1	0	1
	Dyspnoea	12	5	17
	Epistaxis	0	1	1
	Hypoxia	1	0	1
	Nasal discomfort	1	0	1
	Nocturnal dyspnoea	1	0	1
	Oropharyngeal pain	8	0	8
	Pharyngeal swelling	1	0	1
	Pulmonary embolism	2	0	2
	Pulmonary infarction	1	0	1
	Pulmonary pain	0	1	1

	Respiration abnormal	1	0	1
	Respiratory disorder	14	3	17
	Rhinalgia	1	0	1
	Rhinorrhoea	1	0	1
	Sputum discoloured	1	0	1
	Wheezing	1	0	1
Skin and subcutaneous tissue disorders	Angioedema	1	0	1
	Blister	0	1	1
	Cold sweat	1	0	1
	Cutaneous sarcoidosis	1	0	1
	Erythema	4	3	7
	Erythema nodosum	1	0	1
	Hyperhidrosis	9	2	11
	Petechiae	1	0	1
	Pruritus	5	1	6
	Psoriasis	0	1	1
	Rash	3	4	7
	Rash erythematous	1	0	1
	Rash maculo-papular	1	0	1
	Sensitive skin	0	1	1
	Skin disorder	17	20	37
	Skin reaction	0	1	1
	Urticaria	4	2	6
Vascular disorders	Artery dissection	1	0	1
	Blood pressure fluctuation	1	0	1
	Cyanosis	1	0	1
	Deep vein thrombosis	1	0	1
	Diastolic hypertension	1	0	1
	Flushing	1	0	1
	Haematoma	1	1	2
	Hot flush	1	0	1
	Hypertension	3	1	4
	Hypertensive crisis	1	0	1
	Hypotension	5	0	5
	Infarction	1	0	1
	Lymphoedema	1	0	1
	Pallor	2	2	4
	Thrombosis	1	2	3
	Vasculitis	1	0	1
Total		2300	609	2.909