

Summary Tabulation 10-05-2021

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	6	1	7
	Thrombocytopenia	2	0	2
Cardiac disorders	Arrhythmia	1	0	1
	Atrial fibrillation	1	0	1
	Bradycardia	1	0	1
	Cardiac failure	2	0	2
	Cardiovascular disorder	9	1	10
	Coronary artery occlusion	1	0	1
	Palpitations	2	1	3
	Tachycardia	4	2	6
Ear and labyrinth disorders	Ear pain	1	0	1
	Tinnitus	5	0	5
	Vertigo	3	1	4
Endocrine disorders	Hypothyroidism	1	0	1
Eye disorders	Conjunctival haemorrhage	1	0	1
	Eye oedema	0	1	1
	Eye pain	1	0	1
	Lacrimation increased	0	1	1
	Scleritis	1	0	1
	Swelling of eyelid	0	1	1
	Vision blurred	1	0	1
Gastrointestinal disorders	Abdominal pain	3	1	4
	Abdominal pain upper	1	1	2
	Aphthous ulcer	1	0	1
	Diarrhoea	4	1	5
	Lip swelling	2	0	2
	Nausea	66	15	81
	Paraesthesia oral	1	1	2
	Retching	0	1	1
	Swollen tongue	1	0	1
	Vomiting	11	4	15
General disorders and administration site conditions	Adverse reaction	0	1	1
	Asthenia	9	2	11
	Axillary pain	0	2	2

	Chest discomfort	2	0	2
	Chest pain	1	1	2
	Chills	95	24	119
	Cyst	0	1	1
	Death	3	0	3
	Discomfort	1	0	1
	Extensive swelling of vaccinated limb	11	1	12
	Face oedema	0	1	1
	Fatigue	111	30	141
	Feeling abnormal	1	0	1
	Feeling cold	1	1	2
	Feeling hot	2	1	3
	Feeling of body temperature change	1	0	1
	Gait disturbance	1	0	1
	Hyperthermia	0	1	1
	Hypothermia	1	0	1
	Inflammation	1	0	1
	Inflammatory pain	1	0	1
	Influenza like illness	15	2	17
	Injected limb mobility decreased	1	0	1
	Injection site erythema	6	12	18
	Injection site haematoma	1	0	1
	Injection site hypersensitivity	0	1	1
	Injection site induration	2	5	7
	Injection site movement impairment	1	0	1
	Injection site pain	8	11	19
	Injection site paraesthesia	1	0	1
	Injection site pruritus	0	3	3
	Injection site reaction	73	22	95
	Injection site swelling	5	4	9
	Injection site warmth	1	0	1
	Malaise	61	15	76
	Pain	4	0	4
	Peripheral swelling	14	4	18
	Pyrexia	131	37	168
	Sudden death	1	0	1
	Swelling face	1	1	2
	Vaccination site lymphadenopathy	0	1	1
Immune system disorders	Anaphylactic reaction	1	0	1
	Autoimmune disorder	0	1	1
	Hypersensitivity	3	1	4
	Immune system disorder	0	1	1
Infections and infestations	COVID-19	4	0	4
	Erysipelas	1	0	1
	Herpes zoster	1	2	3
	Influenza	1	0	1
	Peritonsillar abscess	1	0	1
	Pneumonia	1	0	1
Injury, poisoning and procedural complications	Exposure via breast milk	1	0	1
	Fall	1	0	1

	Product dose omission issue	1	0	1
Investigations	Blood pressure decreased	2	0	2
	Body temperature abnormal	1	0	1
	Body temperature increased	0	1	1
	C-reactive protein increased	0	1	1
	Heart rate increased	3	0	3
	Heart rate irregular	0	1	1
	Oxygen saturation decreased	1	1	2
	Weight increased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	9	1	10
Musculoskeletal and connective tissue disorders	Arthralgia	71	8	79
	Back pain	1	1	2
	Limb discomfort	1	0	1
	Muscle spasms	0	1	1
	Muscular weakness	4	1	5
	Musculoskeletal discomfort	1	0	1
	Musculoskeletal stiffness	3	2	5
	Myalgia	109	40	149
	Neck pain	1	2	3
	Pain in extremity	6	6	12
	Pain in jaw	1	0	1
Nervous system disorders	Altered state of consciousness	1	0	1
	Balance disorder	2	0	2
	Cerebrovascular accident	1	0	1
	Dizziness	12	2	14
	Dysarthria	1	0	1
	Dysgeusia	2	0	2
	Facial paralysis	0	2	2
	Headache	109	31	140
	Hypokinesia	1	0	1
	Hyporeflexia	1	0	1
	Loss of consciousness	0	1	1
	Migraine	3	1	4
	Nervous system disorder	3	0	3
	Paraesthesia	0	1	1
	Paralysis	1	0	1
	Paresis	1	0	1
	Presyncope	0	2	2
	Seizure	0	1	1
	Sensorimotor disorder	1	0	1
	Somnolence	2	0	2
	Syncope	3	3	6
Taste disorder	1	0	1	
Tremor	1	0	1	
Psychiatric disorders	Confusional state	0	1	1
	Insomnia	3	0	3
Renal and urinary disorders	Chromaturia	1	0	1
	Polyuria	1	0	1
	Renal disorder	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1

	Asphyxia	1	0	1
	Cough	3	1	4
	Dyspnoea	3	1	4
	Oropharyngeal pain	4	0	4
	Pharyngeal swelling	1	0	1
	Pulmonary embolism	2	0	2
	Pulmonary infarction	1	0	1
	Respiration abnormal	1	0	1
	Respiratory disorder	9	3	12
Skin and subcutaneous tissue disorders	Erythema	1	2	3
	Hyperhidrosis	5	1	6
	Petechiae	1	0	1
	Pruritus	2	0	2
	Psoriasis	0	1	1
	Rash	3	2	5
	Rash erythematous	1	0	1
	Rash maculo-papular	1	0	1
	Sensitive skin	0	1	1
	Skin disorder	6	11	17
	Urticaria	2	2	4
Vascular disorders	Cyanosis	1	0	1
	Diastolic hypertension	1	0	1
	Flushing	1	0	1
	Haematoma	1	0	1
	Hypertension	3	0	3
	Hypotension	2	0	2
	Pallor	2	2	4
	Thrombosis	1	1	2
	Vasculitis	1	0	1
Total		1148	363	1 511