

## Summary Tabulation 04.05.2021

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
	Lymphadenopathy	6	1	7
	Thrombocytopenia	2	0	2
Cardiac disorders	Bradycardia	1	0	1
	Cardiovascular disorder	7	1	8
	Coronary artery occlusion	1	0	1
	Palpitations	2	1	3
	Tachycardia	2	2	4
Ear and labyrinth disorders	Ear pain	1	0	1
	Tinnitus	4	0	4
	Vertigo	3	1	4
Endocrine disorders	Hypothyroidism	1	0	1
Eye disorders	Conjunctival haemorrhage	1	0	1
	Eye oedema	0	1	1
	Scleritis	1	0	1
	Swelling of eyelid	0	1	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	1	0	1
	Nausea	55	15	70
	Paraesthesia oral	1	1	2
	Retching	0	1	1
	Swollen tongue	1	0	1
	Vomiting	10	4	14
General disorders and administration site conditions	Adverse reaction	0	1	1
	Asthenia	8	2	10
	Axillary pain	0	2	2
	Chest discomfort	2	0	2
	Chest pain	1	1	2
	Chills	80	24	104
	Cyst	0	1	1
	Discomfort	1	0	1
	Extensive swelling of vaccinated limb	10	1	11
	Face oedema	0	1	1

	Fatigue	91	29	120
	Feeling abnormal	1	0	1
	Feeling cold	0	1	1
	Feeling hot	2	1	3
	Feeling of body temperature change	1	0	1
	Hyperthermia	0	1	1
	Inflammation	1	0	1
	Inflammatory pain	1	0	1
	Influenza like illness	12	2	14
	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	10	18
	Injection site paraesthesia	1	0	1
	Injection site pruritus	0	3	3
	Injection site reaction	62	21	83
	Injection site swelling	5	4	9
	Injection site warmth	1	0	1
	Malaise	50	15	65
	Pain	4	0	4
	Peripheral swelling	13	4	17
	Pyrexia	115	37	152
	Sudden death	1	0	1
	Swelling face	0	1	1
	Vaccination site lymphadenopathy	0	1	1
Immune system disorders	Anaphylactic reaction	1	0	1
	Autoimmune disorder	0	1	1
	Hypersensitivity	2	1	3
	Immune system disorder	0	1	1
Infections and infestations	COVID-19	3	0	3
	Erysipelas	1	0	1
	Herpes zoster	1	1	2
	Influenza	1	0	1
	Peritonsillar abscess	1	0	1
Injury, poisoning and procedural complications	Exposure via breast milk	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	7	1	8
Musculoskeletal and connective tissue disorders	Arthralgia	58	8	66
	Back pain	1	1	2

	Limb discomfort	1	0	1
	Muscle spasms	0	1	1
	Muscular weakness	3	1	4
	Musculoskeletal discomfort	1	0	1
	Musculoskeletal stiffness	3	2	5
	Myalgia	96	40	136
	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
	Cerebrovascular accident	1	0	1
	Dizziness	7	2	9
	Dysarthria	1	0	1
	Dysgeusia	2	0	2
	Facial paralysis	0	1	1
	Headache	92	31	123
	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	1	0	1
	Syncope	2	3	5
	Taste disorder	1	0	1
Psychiatric disorders	Confusional state	0	1	1
	Insomnia	3	0	3
Renal and urinary disorders	Chromaturia	1	0	1
	Renal disorder	1	0	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Asphyxia	1	0	1
	Cough	2	1	3
	Dyspnoea	2	1	3
	Oropharyngeal pain	3	0	3
	Pharyngeal swelling	1	0	1
	Pulmonary embolism	1	0	1
	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	5	11	16
	Urticaria	1	2	3
Vascular disorders	Cyanosis	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
<b>Total</b>		<b>969</b>	<b>357</b>	<b>1.326</b>