

Summary Tabulation 06-04-2021

Active Substance (High Level)		COVID-19 MRNA VACCINE MODERNA (CX-024414)		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Lymphadenopathy	6	1	7
	Thrombocytopenia	1	0	1
Cardiac disorders	Bradycardia	1	0	1
	Cardiovascular disorder	4	0	4
	Palpitations	2	1	3
	Tachycardia	2	2	4
Ear and labyrinth disorders	Ear pain	1	0	1
	Tinnitus	1	0	1
	Vertigo	1	1	2
Endocrine disorders	Hypothyroidism	1	0	1
Eye disorders	Eye oedema	0	1	1
	Scleritis	1	0	1
	Swelling of eyelid	0	1	1
Gastrointestinal disorders	Abdominal pain	1	1	2
	Abdominal pain upper	1	1	2
	Diarrhoea	2	1	3
	Nausea	30	15	45
	Paraesthesia oral	1	1	2
	Retching	0	1	1
	Vomiting	3	4	7
General disorders and administration site conditions	Asthenia	6	2	8
	Axillary pain	0	2	2
	Chest discomfort	2	0	2
	Chest pain	1	1	2
	Chills	41	24	65
	Cyst	0	1	1
	Face oedema	0	1	1
	Fatigue	41	28	69
	Feeling cold	0	1	1
	Feeling hot	1	1	2
	Feeling of body temperature change	1	0	1
	General physical health deterioration	1	0	1
	Hyperthermia	0	1	1
	Inflammation	1	0	1
	Influenza like illness	5	1	6

	Injected limb mobility decreased	1	0	1
	Injection site erythema	5	12	17
	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	6	10	16
	Injection site paraesthesia	1	0	1
	Injection site pruritus	0	3	3
	Injection site reaction	26	20	46
	Injection site swelling	4	4	8
	Injection site warmth	1	0	1
	Malaise	32	14	46
	Pain	3	0	3
	Peripheral swelling	12	4	16
	Pyrexia	53	37	90
	Swelling face	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	1	0	1
	Herpes zoster	0	1	1
	Peritonsillar abscess	1	0	1
Investigations	Body temperature abnormal	1	0	1
	Body temperature increased	0	1	1
	C-reactive protein increased	0	1	1
	Heart rate increased	1	0	1
	Heart rate irregular	0	1	1
	Oxygen saturation decreased	1	1	2
Metabolism and nutrition disorders	Decreased appetite	4	1	5
Musculoskeletal and connective tissue disorders	Arthralgia	17	8	25
	Back pain	0	1	1
	Limb discomfort	1	0	1
	Muscle spasms	0	1	1
	Muscular weakness	2	1	3
	Musculoskeletal discomfort	1	0	1
	Musculoskeletal stiffness	3	2	5
	Myalgia	44	40	84
	Neck pain	1	2	3
	Pain in extremity	5	6	11
Nervous system disorders	Dizziness	3	1	4
	Dysgeusia	1	0	1
	Epilepsy	1	0	1
	Headache	46	31	77
	Hypokinesia	1	0	1
	Hyporeflexia	1	0	1
	Loss of consciousness	0	1	1
	Migraine	2	1	3
	Nervous system disorder	2	0	2

	Paraesthesia	0	1	1
	Paresis	1	0	1
	Presyncope	0	2	2
	Seizure	1	1	2
	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	1	0	1
Respiratory, thoracic and mediastinal disorders	Cough	1	1	2
	Dyspnoea	0	1	1
	Oropharyngeal pain	2	0	2
	Pharyngeal swelling	1	0	1
	Respiratory disorder	5	2	7
Skin and subcutaneous tissue disorders	Erythema	1	2	3
	Hyperhidrosis	3	1	4
	Pruritus	2	0	2
	Psoriasis	0	1	1
	Rash	2	2	4
	Rash maculo-papular	1	0	1
	Sensitive skin	0	1	1
	Skin disorder	3	10	13
	Urticaria	1	2	3
Vascular disorders	Flushing	1	0	1
	Hypertension	2	0	2
	Pallor	2	2	4
Total		485	342	827