

Summary Tabulation 21-09-2021

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	7	1	8
	Lymph node pain	0	1	1
	Lymphadenitis	1	0	1
	Lymphadenopathy	31	6	37
	Splenic infarction	1	0	1
	Thrombocytopenia	5	0	5
Cardiac disorders	Acute myocardial infarction	2	0	2
	Angina pectoris	2	0	2
	Arrhythmia	4	1	5
	Atrial fibrillation	4	0	4
	Atrial flutter	1	0	1
	Bradycardia	1	0	1
	Cardiac arrest	3	0	3
	Cardiac discomfort	1	1	2
	Cardiac failure	2	0	2
	Cardiac tamponade	1	0	1
	Cardiovascular disorder	28	2	30
	Coronary artery occlusion	1	0	1
	Extrasystoles	4	0	4
	Heart alternation	1	0	1
	Myocardial ischaemia	1	0	1
	Myocarditis	4	0	4
	Palpitations	22	6	28
	Pericarditis	7	1	8
	Sinus bradycardia	1	0	1
	Supraventricular extrasystoles	1	0	1
Tachycardia	10	8	18	
Ventricular extrasystoles	1	0	1	
Congenital, familial and genetic disorders	Limb malformation	1	0	1
Ear and labyrinth disorders	Deafness	1	0	1
	Ear discomfort	5	1	6
	Ear pain	3	0	3
	Hyperacusis	4	1	5
	Inner ear disorder	0	1	1
	Tinnitus	9	4	13
	Vertigo	12	15	27
Endocrine disorders	Goitre	2	0	2

	Hypothyroidism	1	0	1
	Thyroiditis subacute	0	1	1
Eye disorders	Blindness	2	1	3
	Conjunctival haemorrhage	2	1	3
	Diplopia	2	1	3
	Dry eye	0	2	2
	Eye discharge	1	0	1
	Eye haemorrhage	1	0	1
	Eye oedema	0	1	1
	Eye pain	4	2	6
	Eye swelling	1	0	1
	Eyelid pain	0	1	1
	Eyelids pruritus	1	0	1
	Iridocyclitis	0	1	1
	Lacrimation increased	0	1	1
	Ocular discomfort	1	0	1
	Ocular hyperaemia	0	1	1
	Photophobia	4	1	5
	Retinal detachment	1	0	1
	Retinal vein thrombosis	0	1	1
	Scleritis	1	0	1
	Strabismus	1	0	1
	Swelling of eyelid	0	1	1
	Uveitis	0	1	1
	Vision blurred	6	0	6
	Visual impairment	5	5	10
Gastrointestinal disorders	Abdominal discomfort	4	1	5
	Abdominal distension	0	1	1
	Abdominal pain	14	5	19
	Abdominal pain lower	1	0	1
	Abdominal pain upper	13	5	18
	Abdominal rigidity	0	1	1
	Aphthous ulcer	1	1	2
	Constipation	1	0	1
	Diarrhoea	30	9	39
	Dry mouth	2	0	2
	Dyspepsia	4	0	4
	Dysphagia	2	0	2
	Eructation	1	0	1
	Gastrointestinal disorder	0	1	1
	Gastrointestinal pain	1	0	1
	Haematochezia	1	0	1
	Haemorrhoids	1	1	2
	Hypoaesthesia oral	0	1	1
	Lip swelling	3	1	4
	Mouth swelling	0	1	1
	Nausea	401	94	495
	Odynophagia	1	0	1
	Oesophageal spasm	1	0	1
	Paraesthesia oral	2	1	3

	Retching	0	2	2
	Swollen tongue	3	2	5
	Toothache	2	0	2
	Vomiting	63	17	80
General disorders and administration site conditions	Asthenia	29	11	40
	Axillary pain	6	15	21
	Chest discomfort	5	6	11
	Chest pain	16	9	25
	Chills	546	147	693
	Condition aggravated	2	1	3
	Cyst	0	1	1
	Death	9	0	9
	Decreased activity	1	0	1
	Discomfort	6	1	7
	Disease recurrence	1	0	1
	Extensive swelling of vaccinated limb	151	45	196
	Face oedema	1	1	2
	Facial pain	1	0	1
	Fatigue	675	207	882
	Feeling abnormal	5	8	13
	Feeling cold	12	4	16
	Feeling hot	15	5	20
	Feeling of body temperature change	7	1	8
	Gait disturbance	7	0	7
	General physical health deterioration	1	0	1
	Hangover	3	0	3
	Hyperthermia	0	1	1
	Hypothermia	1	0	1
	Illness	2	1	3
	Induration	0	1	1
	Inflammation	1	1	2
	Inflammatory pain	1	0	1
	Influenza like illness	78	18	96
	Injected limb mobility decreased	1	0	1
	Injection site bruising	1	0	1
	Injection site dermatitis	1	0	1
	Injection site discomfort	1	0	1
	Injection site erythema	37	26	63
	Injection site haematoma	3	1	4
	Injection site hypersensitivity	1	2	3
	Injection site induration	7	7	14
	Injection site inflammation	2	2	4
	Injection site irritation	1	0	1
	Injection site lymphadenopathy	1	0	1
	Injection site macule	0	1	1
	Injection site movement impairment	7	0	7
	Injection site necrosis	0	1	1
	Injection site oedema	1	0	1
	Injection site pain	46	26	72
	Injection site paraesthesia	2	0	2

	Injection site plaque	2	1	3
	Injection site pruritus	7	4	11
	Injection site rash	2	0	2
	Injection site reaction	487	129	616
	Injection site swelling	21	18	39
	Injection site warmth	13	1	14
	Malaise	453	96	549
	Mass	0	1	1
	Oedema peripheral	4	2	6
	Pain	22	11	33
	Peripheral swelling	28	13	41
	Pyrexia	633	176	809
	Sense of oppression	1	1	2
	Sensitivity to weather change	0	1	1
	Sudden death	1	0	1
	Swelling	2	2	4
	Swelling face	2	2	4
	Systemic inflammatory response syndrome	1	1	2
	Terminal state	1	0	1
	Thirst	3	1	4
	Vaccination failure	1	0	1
	Vaccination site bruising	0	1	1
	Vaccination site erythema	2	12	14
	Vaccination site lymphadenopathy	0	2	2
	Vaccination site mass	1	2	3
	Vaccination site movement impairment	2	2	4
	Vaccination site pain	6	14	20
	Vaccination site plaque	0	1	1
	Vaccination site pruritus	0	1	1
	Vaccination site reaction	0	1	1
	Vaccination site swelling	3	3	6
	Vaccination site warmth	0	3	3
Hepatobiliary disorders	Hepatitis	1	1	2
	Liver disorder	3	1	4
Immune system disorders	Allergy to vaccine	1	1	2
	Anaphylactic reaction	5	2	7
	Anaphylactic shock	4	1	5
	Autoimmune disorder	1	1	2
	Drug hypersensitivity	0	1	1
	Hypersensitivity	6	2	8
	Immune system disorder	0	1	1
Infections and infestations	Bronchitis	0	1	1
	COVID-19	20	2	22
	COVID-19 pneumonia	1	0	1
	Cellulitis	1	1	2
	Erysipelas	3	0	3
	Herpes virus infection	0	1	1
	Herpes zoster	8	24	32
	Herpes zoster meningoencephalitis	1	0	1
	Infection	0	1	1

	Influenza	4	0	4
	Localised infection	1	0	1
	Meningitis viral	1	0	1
	Mucosal infection	2	0	2
	Myelitis	1	0	1
	Nasopharyngitis	2	5	7
	Ophthalmic herpes zoster	1	0	1
	Oral herpes	1	0	1
	Peritonsillar abscess	1	0	1
	Pneumonia	3	0	3
	Sinusitis	1	0	1
	Skin infection	1	0	1
	Vaccination site joint infection	1	0	1
	Vaccination site pustule	0	1	1
	Viral infection	1	0	1
Injury, poisoning and procedural complications	Airway burns	1	0	1
	Cartilage injury	1	0	1
	Contusion	2	6	8
	Exposure via breast milk	1	1	2
	Fall	5	1	6
	Heat stroke	0	1	1
	Inappropriate schedule of product	0	31	31
	Incorrect dose administered	0	1	1
	Joint injury	1	0	1
	Muscle rupture	0	1	1
	Musculoskeletal injury	1	0	1
	Off label use	0	2	2
	Product administered to patient of	0	1	1
	Product dose omission issue	2	3	5
	Tracheal injury	1	0	1
	Vaccination complication	2	5	7
	Wound	1	1	2
	Wrong technique in product usage process	0	1	1
Investigations	Antibody test negative	0	1	1
	Arteriogram carotid abnormal	1	0	1
	Biopsy artery	1	0	1
	Blood fibrinogen increased	1	0	1
	Blood glucose increased	0	1	1
	Blood pressure decreased	4	3	7
	Blood pressure increased	1	4	5
	Blood prolactin decreased	1	0	1
	Body temperature abnormal	1	0	1
	Body temperature decreased	1	0	1
	Body temperature fluctuation	2	0	2
	Body temperature increased	2	1	3
	C-reactive protein increased	6	1	7
	Ejection fraction decreased	1	0	1
	Electrocardiogram ST segment elevation	2	0	2
	Fibrin D dimer increased	4	0	4
	Heart rate decreased	1	0	1

	Heart rate increased	9	3	12
	Heart rate irregular	1	1	2
	Hormone level abnormal	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
	Red blood cell sedimentation rate increased	1	0	1
	Respiratory rate increased	1	0	1
	SARS-CoV-2 antibody test positive	1	0	1
	SARS-CoV-2 test negative	2	0	2
	SARS-CoV-2 test positive	2	1	3
	Serum ferritin increased	1	0	1
	Troponin increased	4	0	4
	Weight decreased	4	1	5
	Weight increased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	27	6	33
	Dehydration	0	3	3
	Folate deficiency	1	0	1
	Vitamin B12 deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	362	98	460
	Axillary mass	3	5	8
	Back pain	15	6	21
	Bone pain	2	0	2
	Groin pain	0	1	1
	Joint stiffness	1	0	1
	Joint swelling	2	3	5
	Limb discomfort	13	10	23
	Muscle fatigue	0	1	1
	Muscle rigidity	3	0	3
	Muscle spasms	4	4	8
	Muscle twitching	1	0	1
	Muscular weakness	10	3	13
	Musculoskeletal chest pain	0	1	1
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal stiffness	23	6	29
	Myalgia	601	196	797
	Neck pain	7	4	11
	Pain in extremity	58	30	88
	Pain in jaw	1	0	1
	Periarthritis	1	1	2
	Polymyalgia rheumatica	0	1	1
	Rheumatic disorder	1	0	1
	Torticollis	2	0	2
Nervous system disorders	Ageusia	5	2	7
	Altered state of consciousness	1	0	1
	Amnesia	0	1	1
	Anosmia	1	0	1
	Aphasia	1	1	2

Balance disorder	4	3	7
Bell's palsy	0	1	1
Burning sensation	3	4	7
Central pain syndrome	1	0	1
Cerebral artery thrombosis	1	0	1
Cerebral haemorrhage	1	0	1
Cerebral thrombosis	1	0	1
Cerebral venous sinus thrombosis	1	0	1
Cerebrovascular accident	5	1	6
Cognitive disorder	1	0	1
Coordination abnormal	3	0	3
Diplegia	1	0	1
Disturbance in attention	5	0	5
Dizziness	42	9	51
Dizziness postural	1	0	1
Dysarthria	1	0	1
Dysgeusia	2	0	2
Dysstasia	2	1	3
Dystonia	1	0	1
Electric shock sensation	0	1	1
Facial paralysis	5	4	9
Formication	1	0	1
Guillain-Barre syndrome	2	0	2
Haemorrhagic transformation stroke	1	0	1
Head discomfort	6	0	6
Headache	620	178	798
Hemianopia	0	1	1
Hemiparesis	1	0	1
Hemiplegia	2	0	2
Hyperaesthesia	1	1	2
Hypersomnia	0	1	1
Hypoaesthesia	10	7	17
Hypokinesia	1	0	1
Hyporeflexia	1	0	1
Intention tremor	1	0	1
Ischaemic stroke	1	0	1
Lethargy	1	0	1
Loss of consciousness	7	2	9
Memory impairment	2	0	2
Meningism	1	0	1
Migraine	16	5	21
Migraine with aura	1	0	1
Monoplegia	1	0	1
Motor dysfunction	1	0	1
Movement disorder	2	0	2
Muscle contractions involuntary	3	0	3
Nervous system disorder	16	2	18
Neuralgia	2	2	4
Neuropathy peripheral	0	1	1
Paraesthesia	13	10	23

	Paralysis	1	0	1
	Paraplegia	1	0	1
	Paresis	1	0	1
	Parosmia	2	0	2
	Post herpetic neuralgia	0	2	2
	Presyncope	6	4	10
	Radiculopathy	1	0	1
	Retinal migraine	0	1	1
	Seizure	1	2	3
	Sensorimotor disorder	1	0	1
	Sensory disturbance	1	0	1
	Sensory loss	1	0	1
	Sleep deficit	2	0	2
	Somnolence	7	2	9
	Speech disorder	0	1	1
	Spinal artery embolism	1	0	1
	Syncope	17	4	21
	Taste disorder	3	0	3
	Tension headache	0	1	1
	Transient ischaemic attack	1	0	1
	Tremor	10	2	12
	Trigeminal neuralgia	2	1	3
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	3	1	4
	Morning sickness	1	0	1
	Premature baby	1	0	1
	Uterine hypertonus	1	0	1
Psychiatric disorders	Abnormal dreams	3	0	3
	Agoraphobia	1	0	1
	Anxiety	0	2	2
	Apathy	1	0	1
	Confusional state	4	1	5
	Delirium	1	0	1
	Depressed mood	0	1	1
	Disorientation	0	1	1
	Eating disorder	1	0	1
	Emotional disorder	1	1	2
	Fear	1	1	2
	Head banging	3	0	3
	Illusion	1	0	1
	Insomnia	17	5	22
	Mental disorder	1	0	1
	Mood altered	1	0	1
	Mood swings	1	0	1
	Nervousness	3	0	3
	Nightmare	2	0	2
	Panic reaction	1	0	1
	Poor quality sleep	2	1	3
	Restlessness	2	0	2
	Sleep disorder	6	1	7
	Sleep disorder due to general medical condition, hypersomnia type	0	1	1

Renal and urinary disorders	Chromaturia	1	0	1
	Dysuria	1	0	1
	Incontinence	0	1	1
	Pollakiuria	1	0	1
	Polyuria	1	0	1
	Renal disorder	2	1	3
	Renal pain	5	1	6
	Strangury	1	0	1
	Urinary incontinence	0	1	1
Reproductive system and breast disorders	Adnexa uteri pain	1	0	1
	Amenorrhoea	2	2	4
	Breast engorgement	1	0	1
	Breast mass	1	0	1
	Breast pain	4	1	5
	Breast swelling	1	1	2
	Cervix disorder	0	1	1
	Dysmenorrhoea	13	2	15
	Heavy menstrual bleeding	9	3	12
	Intermenstrual bleeding	1	2	3
	Menometrorrhagia	1	0	1
	Menstrual disorder	7	4	11
	Menstruation delayed	1	2	3
	Menstruation irregular	10	3	13
	Oligomenorrhoea	3	0	3
	Polymenorrhoea	8	1	9
	Uterine spasm	1	0	1
	Vulval disorder	0	1	1
	Vulvovaginal discomfort	1	0	1
	Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0
Aphonia		1	0	1
Apnoea		1	0	1
Asphyxia		1	0	1
Choking sensation		0	2	2
Cough		9	4	13
Dry throat		1	0	1
Dysphonia		2	0	2
Dyspnoea		27	12	39
Dyspnoea exertional		1	1	2
Epistaxis		0	1	1
Hypoxia		1	0	1
Laryngeal oedema		1	0	1
Mouth breathing		1	0	1
Nasal congestion		4	1	5
Nasal discomfort		2	0	2
Nocturnal dyspnoea		1	1	2
Oropharyngeal pain		20	3	23
Pharyngeal swelling		2	0	2
Pleurisy		0	1	1
Productive cough		1	1	2
Pulmonary embolism		4	0	4

	Pulmonary infarction	1	0	1
	Pulmonary pain	2	1	3
	Respiration abnormal	1	0	1
	Respiratory depth decreased	1	0	1
	Respiratory disorder	20	5	25
	Respiratory distress	3	0	3
	Rhinalgia	1	0	1
	Rhinorrhoea	1	1	2
	Sputum discoloured	1	0	1
	Throat tightness	0	1	1
	Upper respiratory tract congestion	1	0	1
	Wheezing	1	1	2
Skin and subcutaneous tissue disorders	Angioedema	4	0	4
	Blister	1	1	2
	Cold sweat	2	1	3
	Cutaneous sarcoidosis	1	0	1
	Dry skin	2	0	2
	Erythema	9	9	18
	Erythema nodosum	1	0	1
	Hyperhidrosis	25	10	35
	Lividity	1	0	1
	Night sweats	5	1	6
	Pain of skin	3	1	4
	Petechiae	1	0	1
	Photosensitivity reaction	1	0	1
	Pruritus	14	3	17
	Psoriasis	0	1	1
	Rash	9	5	14
	Rash erythematous	4	1	5
	Rash macular	14	5	19
	Rash maculo-papular	1	0	1
	Rash papular	0	1	1
	Rash pruritic	0	1	1
	Sensitive skin	3	3	6
	Skin burning sensation	1	0	1
	Skin discolouration	0	1	1
	Skin disorder	82	55	137
	Skin reaction	1	2	3
	Skin warm	0	1	1
	Urticaria	9	6	15
Social circumstances	Bedridden	0	1	1
	Housebound	1	0	1
	Impaired work ability	1	0	1
	Walking disability	2	0	2
	Water pollution	1	0	1
Surgical and medical procedures	Bed rest	3	0	3
Vascular disorders	Arteritis	1	0	1
	Artery dissection	1	0	1
	Blood pressure fluctuation	3	2	5
	Circulatory collapse	1	0	1

Cyanosis	1	0	1
Deep vein thrombosis	2	0	2
Diastolic hypertension	1	0	1
Flushing	1	0	1
Giant cell arteritis	1	0	1
Haematoma	3	3	6
Haemodynamic instability	1	0	1
Haemorrhage	2	0	2
Hot flush	4	5	9
Hypertension	5	2	7
Hypertensive crisis	2	0	2
Hypotension	9	0	9
Infarction	1	0	1
Lymphoedema	1	0	1
Microangiopathy	0	1	1
Pallor	4	2	6
Peripheral coldness	3	0	3
Phlebitis	1	0	1
Shock	1	0	1
Thrombosis	2	2	4
Varicophlebitis	0	1	1
Varicose vein	1	1	2
Vasculitis	1	0	1
Vein discolouration	1	0	1
Vein disorder	1	0	1
Venous thrombosis	1	1	2
Total	6831	2233	9 064