

Summary Tabulation 2021.07.27

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	6	1	7
	Lymph node pain	0	1	1
	Lymphadenitis	1	0	1
	Lymphadenopathy	17	3	20
	Splenic infarction	1	0	1
	Thrombocytopenia	5	0	5
Cardiac disorders	Acute myocardial infarction	1	0	1
	Angina pectoris	1	0	1
	Arrhythmia	3	1	4
	Atrial fibrillation	2	0	2
	Atrial flutter	1	0	1
	Bradycardia	1	0	1
	Cardiac arrest	3	0	3
	Cardiac discomfort	1	0	1
	Cardiac failure	2	0	2
	Cardiac tamponade	1	0	1
	Cardiovascular disorder	20	2	22
	Coronary artery occlusion	1	0	1
	Extrasystoles	1	0	1
	Heart alternation	1	0	1
	Myocardial ischaemia	1	0	1
	Myocarditis	1	0	1
	Palpitations	15	5	20
	Pericarditis	5	1	6
	Supraventricular extrasystoles	1	0	1
	Tachycardia	7	6	13
Ventricular extrasystoles	1	0	1	
Ear and labyrinth disorders	Deafness	1	0	1
	Ear discomfort	4	0	4
	Ear pain	2	0	2
	Hyperacusis	3	1	4
	Tinnitus	7	3	10
	Vertigo	6	8	14
Endocrine disorders	Goitre	1	0	1
	Hypothyroidism	1	0	1

Eye disorders	Conjunctival haemorrhage	1	1	2
	Diplopia	1	1	2
	Eye oedema	0	1	1
	Eye pain	3	2	5
	Iridocyclitis	0	1	1
	Lacrimation increased	0	1	1
	Ocular discomfort	1	0	1
	Photophobia	2	1	3
	Scleritis	1	0	1
	Swelling of eyelid	0	1	1
	Uveitis	0	1	1
	Vision blurred	3	0	3
	Visual impairment	3	3	6
	Gastrointestinal disorders	Abdominal discomfort	3	1
Abdominal pain		10	2	12
Abdominal pain lower		1	0	1
Abdominal pain upper		6	4	10
Aphthous ulcer		1	0	1
Diarrhoea		21	7	28
Dyspepsia		1	0	1
Eructation		1	0	1
Gastrointestinal disorder		0	1	1
Gastrointestinal pain		1	0	1
Haematochezia		1	0	1
Hypoaesthesia oral		0	1	1
Lip swelling		3	1	4
Mouth swelling		0	1	1
Nausea		251	54	305
Oesophageal spasm		1	0	1
Paraesthesia oral		1	1	2
Retching		0	2	2
Swollen tongue		3	1	4
Toothache		1	0	1
Vomiting	41	11	52	
General disorders and administration site conditions	Asthenia	19	8	27
	Axillary pain	3	9	12
	Chest discomfort	4	5	9
	Chest pain	9	6	15
	Chills	358	81	439
	Condition aggravated	1	1	2
	Cyst	0	1	1
	Death	8	0	8
	Discomfort	3	0	3
	Extensive swelling of vaccinated limb	89	23	112
	Face oedema	1	1	2
	Fatigue	419	116	535
	Feeling abnormal	1	7	8
	Feeling cold	4	3	7
	Feeling hot	10	4	14
	Feeling of body temperature change	4	1	5

Gait disturbance	5	0	5
General physical health deterioration	1	0	1
Hangover	1	0	1
Hyperthermia	0	1	1
Hypothermia	1	0	1
Illness	1	0	1
Induration	0	1	1
Inflammation	1	1	2
Inflammatory pain	1	0	1
Influenza like illness	59	10	69
Injected limb mobility decreased	1	0	1
Injection site bruising	1	0	1
Injection site erythema	15	22	37
Injection site haematoma	2	0	2
Injection site hypersensitivity	0	2	2
Injection site induration	5	6	11
Injection site inflammation	1	1	2
Injection site movement impairment	3	0	3
Injection site necrosis	0	1	1
Injection site oedema	1	0	1
Injection site pain	22	18	40
Injection site paraesthesia	1	0	1
Injection site plaque	1	0	1
Injection site pruritus	4	4	8
Injection site rash	2	0	2
Injection site reaction	316	71	387
Injection site swelling	7	15	22
Injection site warmth	6	1	7
Malaise	271	57	328
Mass	0	1	1
Oedema peripheral	2	0	2
Pain	12	8	20
Peripheral swelling	21	13	34
Pyrexia	416	101	517
Sensitivity to weather change	0	1	1
Sudden death	1	0	1
Swelling	1	2	3
Swelling face	2	2	4
Systemic inflammatory response syndrome	1	0	1
Terminal state	1	0	1
Thirst	0	1	1
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	12	18
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	Liver disorder	3	0	3
Immune system disorders	Allergy to vaccine	1	1	2
	Anaphylactic reaction	5	0	5
	Anaphylactic shock	2	0	2
	Autoimmune disorder	0	1	1
	Drug hypersensitivity	0	1	1
	Hypersensitivity	5	1	6
	Immune system disorder	0	1	1
Infections and infestations	COVID-19	18	1	19
	COVID-19 pneumonia	1	0	1
	Cellulitis	1	0	1
	Erysipelas	3	0	3
	Herpes zoster	5	17	22
	Herpes zoster meningoencephalitis	1	0	1
	Infection	0	1	1
	Influenza	3	0	3
	Localised infection	1	0	1
	Meningitis viral	1	0	1
	Nasopharyngitis	1	2	3
	Peritonsillar abscess	1	0	1
	Pneumonia	2	0	2
	Vaccination site joint infection	1	0	1
	Vaccination site pustule	0	1	1
	Injury, poisoning and procedural complications	Airway burns	1	0
Cartilage injury		1	0	1
Contusion		1	5	6
Exposure via breast milk		1	1	2
Fall		3	1	4
Heat stroke		0	1	1
Inappropriate schedule of product administration		0	30	30
Incorrect dose administered		0	1	1
Musculoskeletal injury		1	0	1
Off label use		0	1	1
Product administered to patient of inappropriate age		0	1	1
Product dose omission issue		2	1	3
Vaccination complication		1	3	4
Wound		0	1	1
Wrong technique in product usage process		0	1	1
Investigations		Biopsy artery	1	0
	Blood fibrinogen increased	1	0	1
	Blood glucose increased	0	1	1
	Blood pressure decreased	3	2	5
	Blood pressure increased	0	2	2
	Body temperature abnormal	1	0	1
	Body temperature decreased	1	0	1
	Body temperature increased	2	1	3
	C-reactive protein increased	3	1	4

	Electrocardiogram ST segment elevation	1	0	1
	Fibrin D dimer increased	3	0	3
	Heart rate increased	5	1	6
	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
	Red blood cell sedimentation rate increased	1	0	1
	SARS-CoV-2 test negative	1	0	1
	SARS-CoV-2 test positive	1	0	1
	Serum ferritin increased	1	0	1
	Troponin increased	1	0	1
	Weight decreased	0	1	1
	Weight increased	2	0	2
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Decreased appetite	19	3	22
	Folate deficiency	1	0	1
	Vitamin B12 deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Arthralgia	238	57	295
	Axillary mass	2	2	4
	Back pain	5	3	8
	Bone pain	1	0	1
	Joint stiffness	1	0	1
	Joint swelling	2	1	3
	Limb discomfort	8	8	16
	Muscle rigidity	3	0	3
	Muscle spasms	2	1	3
	Muscular weakness	8	3	11
	Musculoskeletal chest pain	0	1	1
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal stiffness	12	5	17
	Myalgia	387	114	501
	Neck pain	5	4	9
	Pain in extremity	27	24	51
	Pain in jaw	1	0	1
	Periarthritis	1	0	1
	Polymyalgia rheumatica	0	1	1
	Torticollis	1	0	1
Nervous system disorders	Ageusia	4	2	6
	Altered state of consciousness	1	0	1
	Amnesia	0	1	1
	Anosmia	1	0	1
	Aphasia	0	1	1
	Balance disorder	3	1	4
	Bell's palsy	0	1	1
	Burning sensation	2	4	6
	Central pain syndrome	1	0	1
	Cerebral artery thrombosis	1	0	1
	Cerebral haemorrhage	1	0	1

Cerebral thrombosis	1	0	1
Cerebrovascular accident	5	1	6
Cognitive disorder	1	0	1
Diplegia	1	0	1
Disturbance in attention	1	0	1
Dizziness	31	9	40
Dizziness postural	1	0	1
Dysarthria	1	0	1
Dysgeusia	2	0	2
Dysstasia	0	1	1
Dystonia	1	0	1
Electric shock sensation	0	1	1
Facial paralysis	3	4	7
Guillain-Barre syndrome	2	0	2
Haemorrhagic transformation stroke	1	0	1
Head discomfort	5	0	5
Headache	392	106	498
Hemianopia	0	1	1
Hemiplegia	1	0	1
Hyperaesthesia	1	1	2
Hypoaesthesia	7	4	11
Hypokinesia	1	0	1
Hyporeflexia	1	0	1
Intention tremor	1	0	1
Ischaemic stroke	1	0	1
Loss of consciousness	5	2	7
Memory impairment	1	0	1
Migraine	9	2	11
Monoplegia	1	0	1
Muscle contractions involuntary	1	0	1
Nervous system disorder	7	2	9
Neuralgia	2	0	2
Paraesthesia	8	6	14
Paralysis	1	0	1
Paraplegia	1	0	1
Paresis	1	0	1
Parosmia	2	0	2
Post herpetic neuralgia	0	2	2
Presyncope	5	2	7
Radiculopathy	1	0	1
Retinal migraine	0	1	1
Seizure	1	2	3
Sensorimotor disorder	1	0	1
Sleep deficit	2	0	2
Somnolence	3	1	4
Speech disorder	0	1	1
Spinal artery embolism	1	0	1
Syncope	11	4	15
Taste disorder	3	0	3
Tension headache	0	1	1

	Transient ischaemic attack	1	0	1
	Tremor	2	2	4
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	3	0	3
	Morning sickness	1	0	1
	Premature baby	1	0	1
	Uterine hypertonus	1	0	1
Psychiatric disorders	Abnormal dreams	1	0	1
	Anxiety	0	2	2
	Apathy	1	0	1
	Confusional state	3	1	4
	Eating disorder	1	0	1
	Fear	0	1	1
	Illusion	1	0	1
	Insomnia	10	4	14
	Nervousness	1	0	1
	Nightmare	1	0	1
	Poor quality sleep	1	0	1
	Restlessness	1	0	1
	Sleep disorder	0	1	1
	Sleep disorder due to general medical condition, hypersomnia type	0	1	1
Renal and urinary disorders	Chromaturia	1	0	1
	Polyuria	1	0	1
	Renal disorder	2	0	2
	Renal pain	3	0	3
	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
	Dysmenorrhoea	5	0	5
	Heavy menstrual bleeding	2	3	5
	Intermenstrual bleeding	0	1	1
	Menstrual disorder	3	1	4
	Menstruation delayed	1	0	1
	Menstruation irregular	2	0	2
	Oligomenorrhoea	1	0	1
	Polymenorrhoea	2	0	2
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1
	Aphonia	1	0	1
	Apnoea	1	0	1
	Asphyxia	1	0	1
	Choking sensation	0	2	2
	Cough	6	3	9
	Dry throat	1	0	1
	Dysphonia	1	0	1
	Dyspnoea	18	9	27
	Dyspnoea exertional	0	1	1
	Epistaxis	0	1	1
	Hypoxia	1	0	1
	Nasal congestion	3	1	4

	Nasal discomfort	1	0	1
	Nocturnal dyspnoea	1	1	2
	Oropharyngeal pain	14	2	16
	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 disorder	16	4	20
	Respiratory distress	1	0	1
	Rhinalgia	1	0	1
	Rhinorrhoea	1	1	2
	Sputum discoloured	1	0	1
	Wheezing	1	1	2
Skin and subcutaneous tissue disorders	Angioedema	4	0	4
	Blister	0	1	1
	Cold sweat	1	0	1
	Cutaneous sarcoidosis	1	0	1
	Erythema	5	6	11
	Erythema nodosum	1	0	1
	Hyperhidrosis	17	4	21
	Lividity	1	0	1
	Night sweats	3	0	3
	Pain of skin	2	0	2
	Petechiae	1	0	1
	Pruritus	9	2	11
	Psoriasis	0	1	1
	Rash	5	4	9
	Rash erythematous	3	1	4
	Rash macular	2	2	4
	Rash maculo-papular	1	0	1
	Rash papular	0	1	1
	Rash pruritic	0	1	1
	Sensitive skin	0	3	3
	Skin discolouration	0	1	1
	Skin disorder	42	30	72
	Skin reaction	1	2	3
	Skin warm	0	1	1
	Urticaria	5	2	7
Social circumstances	Bedridden	0	1	1
Vascular disorders	Arteritis	1	0	1
	Artery dissection	1	0	1
	Blood pressure fluctuation	2	2	4
	Cyanosis	1	0	1
	Deep vein thrombosis	1	0	1
	Diastolic hypertension	1	0	1
	Embolism	1	0	1
	Flushing	1	0	1

Giant cell arteritis	1	0	1
Haematoma	3	1	4
Haemorrhage	1	0	1
Hot flush	1	3	4
Hypertension	4	2	6
Hypertensive crisis	1	0	1
Hypotension	7	0	7
Infarction	1	0	1
Lymphoedema	1	0	1
Pallor	2	2	4
Peripheral coldness	1	0	1
Thrombosis	2	2	4
Varicophlebitis	0	1	1
Varicose vein	1	1	2
Vasculitis	1	0	1
Venous thrombosis	1	1	2
Total	4273	1378	5.651

Rows 1 - 402 (All Rows)