

Summary Tabulation 16-11-2021

Active Substance (High Level) COVID-19 VACCINE JANSSEN (AD26.COVS.2.S)

Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	9	2	11
	Disseminated intravascular coagulation	1	0	1
	Haemoglobinaemia	1	0	1
	Haemolysis	1	0	1
	Haemolytic anaemia	1	0	1
	Hypofibrinogenaemia	1	0	1
	Increased tendency to bruise	1	2	3
	Lymph node pain	0	1	1
	Lymphadenopathy	4	3	7
	Red blood cell abnormality	1	0	1
	Splenic infarction	1	0	1
	Splenic vein thrombosis	1	0	1
	Spontaneous haematoma	1	1	2
	Thrombocytopenia	3	0	3
Cardiac disorders	Acute myocardial infarction	3	0	3
	Angina pectoris	2	0	2
	Arrhythmia	3	1	4
	Cardiac arrest	1	0	1
	Cardiac failure	1	0	1
	Cardiac tamponade	1	0	1
	Cardio-respiratory arrest	1	0	1
	Cardiovascular disorder	9	2	11
	Coronary artery thrombosis	1	0	1
	Myocardial fibrosis	1	0	1
	Myocardial infarction	2	0	2
	Myocardial ischaemia	1	0	1
	Myocardial oedema	1	0	1
	Myocarditis	4	0	4
	Palpitations	9	8	17
	Pericarditis	2	1	3
	Tachycardia	2	6	8
Ear and labyrinth disorders	Deafness	3	1	4
	Ear discomfort	0	1	1
	Ear pain	3	3	6
	Hyperacusis	2	0	2

	Hypoacusis	2	0	2
	Inner ear disorder	0	1	1
	Motion sickness	1	0	1
	Tinnitus	14	8	22
	Vertigo	12	13	25
	Vestibular disorder	1	0	1
Eye disorders	Acute macular neuroretinopathy	1	1	2
	Altered visual depth perception	1	0	1
	Asthenopia	0	1	1
	Blindness	0	1	1
	Blindness unilateral	1	0	1
	Diplopia	1	0	1
	Eye movement disorder	1	0	1
	Eye pain	1	2	3
	Eye swelling	1	1	2
	Lacrimation increased	2	0	2
	Ocular hyperaemia	0	1	1
	Photophobia	2	0	2
	Swelling of eyelid	1	0	1
	Vision blurred	3	7	10
	Visual acuity reduced	2	0	2
	Visual impairment	4	2	6
Gastrointestinal disorders	Abdominal discomfort	2	0	2
	Abdominal distension	0	1	1
	Abdominal pain	17	3	20
	Abdominal pain lower	0	1	1
	Abdominal pain upper	4	5	9
	Aphthous ulcer	1	0	1
	Chapped lips	0	1	1
	Constipation	1	0	1
	Dental discomfort	1	0	1
	Diarrhoea	15	5	20
	Dry mouth	0	1	1
	Dyspepsia	1	0	1
	Dysphagia	2	0	2
	Faeces discoloured	1	0	1
	Flatulence	1	0	1
	Frequent bowel movements	1	0	1
	Gastrointestinal disorder	0	1	1
	Haematemesis	1	0	1
	Hypoaesthesia oral	1	1	2
	Intestinal ischaemia	1	0	1
	Lip swelling	1	1	2
	Mesenteric vein thrombosis	1	0	1
	Mouth swelling	1	0	1
	Nausea	184	58	242
	Odynophagia	0	1	1
	Oral pain	0	1	1
	Palatal disorder	1	0	1
	Pancreatitis	1	0	1

	Pancreatitis acute	1	0	1
	Small intestinal haemorrhage	1	0	1
	Swollen tongue	1	0	1
	Tongue coated	1	1	2
	Vomiting	23	13	36
General disorders and administration site conditions	Administration site pain	1	0	1
	Application site pain	0	1	1
	Asthenia	22	14	36
	Chest discomfort	13	2	15
	Chest pain	11	4	15
	Chills	279	61	340
	Condition aggravated	3	1	4
	Death	11	0	11
	Decreased activity	1	0	1
	Discomfort	3	3	6
	Disease recurrence	2	0	2
	Exercise tolerance decreased	1	0	1
	Extensive swelling of vaccinated limb	15	5	20
	Face oedema	1	0	1
	Facial pain	0	1	1
	Fatigue	317	121	438
	Feeling abnormal	1	5	6
	Feeling cold	7	5	12
	Feeling hot	4	7	11
	Feeling of body temperature change	4	4	8
	Feeling of relaxation	0	1	1
	Gait disturbance	5	4	9
	Gait inability	0	2	2
	General physical health deterioration	2	0	2
	Illness	2	8	10
	Inflammation	1	0	1
	Influenza like illness	36	20	56
	Injection site bruising	2	0	2
	Injection site discomfort	1	0	1
	Injection site erythema	2	2	4
	Injection site haematoma	1	0	1
	Injection site induration	0	1	1
	Injection site mass	0	1	1
	Injection site movement impairment	2	0	2
	Injection site nodule	1	0	1
	Injection site pain	14	21	35
	Injection site pruritus	0	1	1
	Injection site rash	1	0	1
	Injection site reaction	120	24	144
	Injection site swelling	2	1	3
	Injection site warmth	0	1	1
	Malaise	228	53	281
	Multiple organ dysfunction syndrome	1	0	1
	Oedema	1	0	1
	Oedema peripheral	2	0	2

	Pain	13	12	25
	Peripheral swelling	3	5	8
	Pre-existing condition improved	1	0	1
	Pyrexia	301	121	422
	Sense of oppression	4	0	4
	Sluggishness	1	1	2
	Sudden death	2	0	2
	Swelling	3	0	3
	Temperature regulation disorder	1	0	1
	Therapeutic response unexpected	0	1	1
	Therapy non-responder	5	0	5
	Thirst	1	1	2
	Thirst decreased	1	0	1
	Vaccination failure	3	0	3
	Vaccination site bruising	2	0	2
	Vaccination site swelling	1	0	1
Hepatobiliary disorders	Hepatic failure	1	0	1
	Hepatic pain	1	0	1
	Portal vein thrombosis	1	0	1
Immune system disorders	Anaphylactic reaction	1	0	1
	Autoimmune disorder	3	0	3
	Hypersensitivity	4	4	8
	Immune system disorder	1	0	1
Infections and infestations	Appendicitis	1	0	1
	Bronchitis	1	0	1
	COVID-19	16	9	25
	COVID-19 pneumonia	2	0	2
	Ear infection	0	2	2
	Encephalitis	0	1	1
	Genital herpes	1	1	2
	Herpes ophthalmic	0	1	1
	Herpes simplex	0	1	1
	Herpes zoster	0	2	2
	Hordeolum	1	0	1
	Infection	1	0	1
	Influenza	1	1	2
	Injection site infection	1	0	1
	Meningitis viral	1	0	1
	Nasopharyngitis	1	10	11
	Oral infection	0	1	1
	Pneumonia	2	0	2
	Rash pustular	0	1	1
	Septic shock	1	0	1
	Suspected COVID-19	1	2	3
	Tonsillitis	1	0	1
	Urinary tract infection	0	1	1
Injury, poisoning and procedural complications	Contusion	0	5	5
	Fall	4	1	5
	Inappropriate schedule of product	0	1	1
	Muscle injury	0	1	1

	Nasal injury	1	0	1
	Off label use	1	1	2
	Product administered to patient of	1	0	1
	Product administration error	0	1	1
Investigations	Blood glucose increased	1	0	1
	Blood pressure decreased	3	0	3
	Blood pressure increased	0	2	2
	Body temperature increased	1	2	3
	C-reactive protein increased	5	2	7
	Electrocardiogram repolarisation abnormality	1	0	1
	Eosinophil count increased	0	1	1
	Fibrin D dimer increased	6	0	6
	Heart rate increased	9	3	12
	Heparin-induced thrombocytopenia test	1	0	1
	International normalised ratio abnormal	1	0	1
	Lymph nodes scan abnormal	1	0	1
	Lymphocyte count decreased	0	1	1
	Magnetic resonance imaging heart	1	0	1
	Neutrophil count increased	0	1	1
	Oxygen saturation decreased	1	1	2
	PCO2 decreased	1	0	1
	Pleural fluid analysis abnormal	1	0	1
	Prothrombin time shortened	1	1	2
	SARS-CoV-2 test positive	6	4	10
	Shift to the left	1	0	1
	Troponin abnormal	1	0	1
	Troponin increased	3	0	3
	Weight decreased	1	0	1
	White blood cell count decreased	0	1	1
Metabolism and nutrition disorders	Appetite disorder	1	0	1
	Decreased appetite	13	5	18
	Dehydration	2	0	2
	Fluid retention	0	1	1
Musculoskeletal and connective tissue disorders	Arthralgia	155	38	193
	Arthropathy	1	0	1
	Back pain	13	9	22
	Bone pain	0	2	2
	Bursitis	2	0	2
	Groin pain	1	0	1
	Joint stiffness	1	0	1
	Limb discomfort	8	4	12
	Muscle atrophy	1	0	1
	Muscle spasms	7	5	12
	Muscle tightness	1	1	2
	Muscular weakness	7	7	14
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal pain	2	0	2
	Musculoskeletal stiffness	7	9	16
	Myalgia	270	82	352
	Neck pain	5	5	10

	Neuropathic muscular atrophy	1	0	1
	Nuchal rigidity	1	0	1
	Pain in extremity	20	20	40
	Pain in jaw	0	1	1
	Periarthritis	1	0	1
	Polymyalgia rheumatica	1	0	1
	Temporomandibular joint syndrome	1	0	1
	Torticollis	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiocentric lymphoma	1	0	1
	Colon cancer stage IV	1	0	1
	Metastases to liver	1	0	1
Nervous system disorders	Ageusia	2	1	3
	Allodynia	1	0	1
	Altered state of consciousness	2	0	2
	Anosmia	2	1	3
	Balance disorder	3	2	5
	Bell's palsy	1	0	1
	Burning sensation	1	2	3
	Cerebral haematoma	1	0	1
	Cerebral haemorrhage	3	0	3
	Cerebral venous thrombosis	1	0	1
	Cerebrovascular accident	2	0	2
	Cognitive disorder	1	0	1
	Disturbance in attention	1	3	4
	Dizziness	35	23	58
	Dizziness postural	1	0	1
	Dysgeusia	2	6	8
	Dyskinesia	1	0	1
	Dysstasia	2	4	6
	Electric shock sensation	2	1	3
	Encephalomalacia	1	0	1
	Febrile convulsion	1	0	1
	Head discomfort	3	2	5
	Headache	327	122	449
	Hemiparesis	1	0	1
	Hemiplegia	1	0	1
	Hyperaesthesia	0	1	1
	Hyperreflexia	0	1	1
	Hypersomnia	1	1	2
	Hypoaesthesia	3	1	4
	Hypokinesia	1	0	1
	Hypotonia	1	0	1
	Ischaemic stroke	2	0	2
	Loss of consciousness	5	0	5
	Memory impairment	1	0	1
	Mental impairment	1	0	1
	Migraine	5	2	7
	Monoplegia	1	0	1
	Movement disorder	3	0	3
	Multiple sclerosis	0	1	1

	Narcolepsy	1	0	1
	Nervous system disorder	5	0	5
	Neuralgia	2	3	5
	Neuralgic amyotrophy	1	0	1
	Paraesthesia	15	8	23
	Parosmia	0	2	2
	Partial seizures	1	0	1
	Presyncope	3	0	3
	Psychomotor hyperactivity	1	0	1
	Reduced facial expression	0	1	1
	Restless legs syndrome	0	1	1
	Seizure	1	0	1
	Sensory disturbance	0	2	2
	Sensory loss	2	3	5
	Somnolence	2	1	3
	Speech disorder	0	2	2
	Superior sagittal sinus thrombosis	1	0	1
	Syncope	6	1	7
	Taste disorder	1	1	2
	Tremor	9	11	20
	Trigeminal nerve disorder	0	1	1
Pregnancy, puerperium and perinatal conditions	Foetal death	2	0	2
	High foetal head	1	0	1
Product issues	Suspected counterfeit product	0	1	1
Psychiatric disorders	Alphophobia	0	1	1
	Anxiety	0	1	1
	Apathy	0	1	1
	Confusional state	2	1	3
	Conversion disorder	1	0	1
	Depersonalisation/derealisation disorder	1	0	1
	Depression	1	0	1
	Disorientation	1	1	2
	Emotional distress	0	1	1
	Hallucination	2	0	2
	Head banging	1	0	1
	Insomnia	9	4	13
	Irritability	0	1	1
	Libido decreased	0	1	1
	Mood altered	0	1	1
	Mood swings	1	0	1
	Nightmare	0	1	1
	Paramnesia	0	1	1
	Poor quality sleep	2	3	5
	Restlessness	1	0	1
	Sleep disorder	3	0	3
	Thinking abnormal	0	1	1
Renal and urinary disorders	Acute kidney injury	3	0	3
	Glomerulonephritis membranous	1	0	1
	Haematuria	0	1	1
	Nephrotic syndrome	1	0	1

	Pollakiuria	1	0	1
	Renal disorder	2	0	2
	Renal infarct	1	0	1
	Renal pain	2	2	4
	Renal vein thrombosis	1	0	1
	Urinary retention	1	0	1
	Urine abnormality	1	1	2
Reproductive system and breast disorders	Amenorrhoea	1	10	11
	Breast pain	0	2	2
	Dysmenorrhoea	1	3	4
	Heavy menstrual bleeding	2	8	10
	Hypomenorrhoea	1	1	2
	Intermenstrual bleeding	1	5	6
	Menometrorrhagia	0	1	1
	Menstrual disorder	3	8	11
	Menstruation delayed	1	4	5
	Menstruation irregular	3	7	10
	Oligomenorrhoea	1	3	4
	Pelvic pain	1	0	1
	Polymenorrhoea	2	3	5
	Postmenopausal haemorrhage	2	0	2
	Premenstrual pain	0	1	1
	Testicular pain	1	0	1
	Testicular swelling	1	0	1
	Vaginal haemorrhage	2	4	6
	Vaginal odour	0	1	1
Respiratory, thoracic and mediastinal disorders	Aphonia	0	1	1
	Asphyxia	1	0	1
	Cough	6	7	13
	Dyspnoea	15	14	29
	Dyspnoea at rest	1	0	1
	Dyspnoea exertional	1	0	1
	Epistaxis	1	5	6
	Haemoptysis	0	1	1
	Hyperventilation	3	0	3
	Lung disorder	1	0	1
	Nasal congestion	1	0	1
	Nasal obstruction	0	1	1
	Oropharyngeal discomfort	1	0	1
	Oropharyngeal pain	5	2	7
	Paranasal sinus discomfort	0	1	1
	Pharyngeal swelling	2	0	2
	Pneumothorax	1	0	1
	Productive cough	0	1	1
	Pulmonary embolism	5	0	5
	Pulmonary infarction	1	0	1
	Pulmonary oedema	1	0	1
	Respiratory disorder	3	3	6
	Respiratory distress	2	1	3
	Respiratory failure	4	0	4

	Rhinorrhoea	3	0	3
	Sinus pain	0	1	1
	Sneezing	1	0	1
	Throat irritation	0	1	1
Skin and subcutaneous tissue disorders	Acne	1	0	1
	Blood blister	1	0	1
	Dry skin	1	0	1
	Ecchymosis	0	2	2
	Erythema	0	4	4
	Erythema multiforme	1	0	1
	Henoch-Schonlein purpura	1	0	1
	Hyperhidrosis	21	9	30
	Night sweats	1	1	2
	Pain of skin	0	1	1
	Petechiae	3	2	5
	Piloerection	0	1	1
	Pruritus	3	2	5
	Psoriasis	2	0	2
	Purpura	1	1	2
	Pyoderma gangrenosum	1	0	1
	Rash	5	1	6
	Rash macular	4	0	4
	Rash pruritic	2	0	2
	Sensitive skin	3	0	3
	Skin burning sensation	1	2	3
	Skin disorder	36	9	45
	Skin odour abnormal	2	0	2
	Skin reaction	0	1	1
	Urticaria	4	0	4
Social circumstances	Bedridden	0	1	1
	Housebound	1	0	1
	Impaired driving ability	0	2	2
	Impaired work ability	0	5	5
	Loss of personal independence in daily	1	0	1
	Physical disability	0	1	1
	Pregnancy of partner	0	1	1
	Underimmunisation	0	1	1
Surgical and medical procedures	Bed rest	2	1	3
	Pacemaker generated rhythm	1	0	1
Vascular disorders	Cyanosis	2	0	2
	Deep vein thrombosis	3	0	3
	Haematoma	1	1	2
	Haemorrhage	1	0	1
	Hot flush	5	1	6
	Hypertension	3	3	6
	Hypotension	3	2	5
	Hypovolaemic shock	1	0	1
	Microangiopathy	1	0	1
	Orthostatic hypotension	0	1	1
	Pallor	2	1	3

Peripheral coldness	3	0	3
Phlebitis	1	1	2
Raynaud's phenomenon	1	0	1
Shock	2	0	2
Superficial vein thrombosis	0	1	1
Thrombosis	6	0	6
Vascular pain	0	1	1
Vasodilatation	0	1	1
Vein discolouration	1	0	1
Venous occlusion	1	0	1
Total	3215	1330	4 545