

## Summary Tabulation 14-12-2021

Active Substance (High Level)		COVID-19 VACCINE JANSSEN (AD26.COV2.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	7	3	10
	Pernicious anaemia	1	0	1
	Red blood cell abnormality	1	0	1
	Splenic infarction	1	0	1
	Splenic vein thrombosis	1	0	1
	Spontaneous haematoma	1	1	2
	Thrombocytopenia	4	0	4
Cardiac disorders	Acute myocardial infarction	3	0	3
	Angina pectoris	2	0	2
	Arrhythmia	3	1	4
	Arteriospasm coronary	0	1	1
	Cardiac arrest	2	0	2
	Cardiac failure	1	0	1
	Cardiac tamponade	1	0	1
	Cardio-respiratory arrest	1	0	1
	Cardiomegaly	1	0	1
	Cardiovascular disorder	9	2	11
	Coronary artery thrombosis	1	0	1
	Dilatation atrial	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	10	19
	Pericarditis	2	1	3

	Tachycardia	3	7	10
Ear and labyrinth disorders	Deafness	3	1	4
	Ear discomfort	0	2	2
	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	16	11	27
	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
	Blepharitis	1	0	1
	Blindness	0	1	1
	Blindness unilateral	2	0	2
	Diplopia	2	0	2
	Eye disorder	0	1	1
	Eye movement disorder	1	0	1
	Eye pain	2	2	4
	Eye swelling	1	1	2
	Glaucoma	0	1	1
	Lacrimation increased	2	0	2
	Ocular hyperaemia	0	2	2
	Photophobia	2	0	2
	Retinal artery occlusion	1	0	1
	Swelling of eyelid	1	0	1
	Vision blurred	4	7	11
	Visual acuity reduced	3	0	3
	Visual impairment	4	3	7
Gastrointestinal disorders	Abdominal discomfort	2	1	3
	Abdominal distension	1	1	2
	Abdominal pain	18	3	21
	Abdominal pain lower	0	1	1
	Abdominal pain upper	5	6	11
	Aphthous ulcer	1	0	1
	Chapped lips	0	1	1
	Constipation	1	0	1
	Dental discomfort	1	0	1
	Diarrhoea	15	6	21
	Dry mouth	0	1	1
	Dyspepsia	2	0	2
	Dysphagia	3	0	3
	Faeces discoloured	1	1	2
	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	193	60	253
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	14	37
General disorders and administration site conditions			
Administration site pain	1	0	1
Application site pain	0	1	1
Asthenia	24	14	38
Axillary pain	1	0	1
Chest discomfort	13	2	15
Chest pain	18	6	24
Chills	291	65	356
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	1	2
Extensive swelling of vaccinated limb	15	5	20
Face oedema	1	0	1
Facial pain	0	1	1
Fatigue	338	130	468
Feeling abnormal	1	7	8
Feeling cold	7	5	12
Feeling hot	5	7	12
Feeling of body temperature change	4	5	9
Feeling of relaxation	0	1	1
Gait disturbance	5	4	9
Gait inability	0	2	2
General physical health deterioration	2	0	2
Hypothermia	1	0	1
Illness	2	8	10
Inflammation	1	0	1
Influenza like illness	39	21	60
Injection site bruising	2	0	2

	Injection site discomfort	1	0	1
	Injection site erythema	3	2	5
	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	17	23	40
	Injection site pruritus	0	1	1
	Injection site rash	1	0	1
	Injection site reaction	131	26	157
	Injection site swelling	3	1	4
	Injection site warmth	0	1	1
	Malaise	238	60	298
	Multiple organ dysfunction syndrome	1	0	1
	Oedema	1	0	1
	Oedema peripheral	2	0	2
	Pain	13	14	27
	Peripheral swelling	3	5	8
	Pre-existing condition improved	1	0	1
	Pyrexia	313	128	441
	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	2	2
	Therapy non-responder	5	0	5
	Thirst	1	1	2
	Thirst decreased	1	0	1
	Vaccination failure	4	0	4
	Vaccination site bruising	2	0	2
	Vaccination site swelling	1	0	1
Hepatobiliary disorders	Hepatic failure	1	0	1
	Hepatic pain	1	1	2
	Portal vein thrombosis	1	0	1
Immune system disorders	Anaphylactic reaction	1	0	1
	Autoimmune disorder	3	0	3
	Hypersensitivity	5	5	10
	Immune system disorder	1	0	1
Infections and infestations	Appendicitis	1	0	1
	Bronchitis	2	0	2
	COVID-19	22	11	33
	COVID-19 pneumonia	2	0	2
	Conjunctivitis	1	0	1
	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	1	2	3
	Hordeolum	2	0	2
	Infection	1	0	1
	Influenza	1	1	2
	Injection site infection	1	0	1
	Meningitis viral	1	0	1
	Nasopharyngitis	3	10	13
	Oral infection	0	1	1
	Pharyngitis	1	0	1
	Pneumonia	3	0	3
	Rash pustular	0	1	1
	Rhinitis	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	6	1	7
	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	4	13
	Heparin-induced thrombocytopenia test	1	0	1
	Hormone level abnormal	0	1	1
	International normalised ratio abnormal	1	0	1
	Lipase increased	1	0	1
	Lymph nodes scan abnormal	1	0	1
	Lymphocyte count decreased	0	1	1
	Lymphocyte count increased	0	1	1
	Lymphocyte morphology abnormal	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
	Reticulocyte count increased	1	0	1
	SARS-CoV-2 test positive	7	5	12
	Shift to the left	1	0	1
	Sperm concentration decreased	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	6	19
	Dehydration	2	1	3
	Fluid retention	0	1	1
Musculoskeletal and connective tissue disorders	Arthralgia	171	43	214
	Arthritis	1	0	1
	Arthropathy	1	0	1
	Back pain	13	10	23
	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	6	13
	Muscle tightness	1	1	2
	Muscular weakness	9	8	17
	Musculoskeletal chest pain	1	0	1
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal pain	2	0	2
	Musculoskeletal stiffness	7	9	16
	Myalgia	288	87	375
	Neck pain	6	5	11
	Neuropathic muscular atrophy	1	0	1
	Nuchal rigidity	1	0	1
	Pain in extremity	23	22	45
	Pain in jaw	0	1	1
	Periarthritis	1	0	1
	Polymyalgia rheumatica	1	0	1
	Temporomandibular joint syndrome	1	0	1
	Tendon disorder	0	1	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	5	2	7
Bell's palsy	1	0	1
Burning sensation	2	3	5
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
Facial paralysis	1	0	1
Febrile convulsion	1	0	1
Guillain-Barre syndrome	2	0	2
Head discomfort	3	2	5
Headache	349	128	477
Hemiparesis	1	0	1
Hemiplegia	1	0	1
Hyperaesthesia	0	1	1
Hyperreflexia	0	1	1
Hypersomnia	2	2	4
Hypoaesthesia	4	3	7
Hypokinesia	1	0	1
Hypotonia	1	0	1
Ischaemic stroke	2	0	2
Loss of consciousness	7	0	7
Memory impairment	1	0	1
Mental impairment	1	0	1
Migraine	6	2	8
Miller Fisher syndrome	1	0	1
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	4	3	7
Neuralgic amyotrophy	1	0	1
Ophthalmic migraine	1	0	1
Paraesthesia	15	11	26

	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	2	0	2
	Sensory disturbance	0	3	3
	Sensory loss	2	3	5
	Somnolence	2	2	4
	Speech disorder	1	2	3
	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	Affective disorder	1	0	1
	Aggression	1	0	1
	Algophobia	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
	Depressed mood	1	0	1
	Depression	1	0	1
	Disorientation	1	1	2
	Emotional distress	0	1	1
	Hallucination	2	1	3
	Head banging	1	0	1
	Insomnia	11	5	16
	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
	Bladder disorder	1	0	1
	Glomerulonephritis membranous	1	0	1



	Glomerulonephritis minimal lesion	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	13	14
	Breast pain	0	3	3
	Breast swelling	0	1	1
	Dysmenorrhoea	2	3	5
	Heavy menstrual bleeding	5	9	14
	Hypomenorrhoea	1	1	2
	Intermenstrual bleeding	2	6	8
	Menometrorrhagia	0	1	1
	Menstrual disorder	5	11	16
	Menstruation delayed	1	4	5
	Menstruation irregular	5	9	14
	Oligomenorrhoea	1	5	6
	Pelvic pain	1	0	1
	Polymenorrhoea	3	4	7
	Postmenopausal haemorrhage	2	0	2
	Premenstrual pain	0	1	1
	Testicular pain	1	0	1
	Testicular swelling	1	0	1
	Uterine spasm	0	1	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	7	8	15
	Dyspnoea	17	16	33
	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	2	0	2
	Nasal obstruction	0	1	1
	Oropharyngeal discomfort	1	0	1
	Oropharyngeal pain	5	3	8
	Paranasal sinus discomfort	0	1	1
	Pharyngeal swelling	2	0	2

	Pleurisy	1	0	1	
	Pneumothorax	1	0	1	
	Productive cough	0	1	1	
	Pulmonary embolism	5	0	5	
	Pulmonary infarction	1	0	1	
	Pulmonary oedema	2	0	2	
	Pulmonary pain	0	1	1	
	Respiratory arrest	1	0	1	
	Respiratory disorder	3	3	6	
	Respiratory distress	2	1	3	
	Respiratory failure	4	0	4	
	Rhinorrhoea	5	0	5	
	Sinus pain	0	1	1	
	Sneezing	3	0	3	
	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	22	9	31	
	Night sweats	1	1	2	
	Pain of skin	0	1	1	
	Petechiae	3	2	5	
	Piloerection	0	1	1	
	Pruritus	4	2	6	
	Psoriasis	3	0	3	
	Purpura	1	1	2	
	Pyoderma gangrenosum	1	0	1	
	Rash	7	1	8	
	Rash erythematous	1	0	1	
	Rash macular	4	0	4	
	Rash papular	1	0	1	
	Rash pruritic	3	0	3	
	Sensitive skin	3	0	3	
	Skin burning sensation	1	2	3	
	Skin discolouration	0	1	1	
	Skin disorder	39	11	50	
	Skin odour abnormal	2	0	2	
	Skin reaction	0	1	1	
	Urticaria	5	0	5	
	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 activities	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	4	0	4
	Haematoma	1	1	2
	Haemorrhage	1	0	1
	Hot flush	5	1	6
	Hypertension	4	3	7
	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	7	0	7
	Vascular pain	0	1	1
	Vasodilatation	0	1	1
	Vein discolouration	1	0	1
	Venous occlusion	1	0	1
<b>Total</b>		<b>3479</b>	<b>1459</b>	<b>4.938</b>