

Summary Tabulation 31.05.2022

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	2	2
	Lymphadenopathy	8	7	15
	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
Angina pectoris		6	0	6
Arrhythmia		5	0	5
Arteriospasm coronary		1	0	1
Cardiac arrest		2	0	2
Cardiac discomfort		2	2	4
Cardiac disorder		1	0	1
Cardiac failure		1	0	1
Cardiac tamponade		1	0	1
Cardio-respiratory arrest		1	0	1
Cardiomegaly		1	0	1
Cardiovascular disorder		11	2	13
Coronary artery thrombosis		1	0	1
Dilatation atrial		1	0	1
Extrasystoles		0	1	1
Myocardial fibrosis		1	0	1
Myocardial infarction		2	0	2
Myocardial ischaemia		1	0	1
Myocardial oedema		1	0	1
Myocarditis		2	0	2
Myopericarditis	2	0	2	

	Palpitations	13	14	27
	Pericarditis	4	0	4
	Sinus tachycardia	0	1	1
	Tachycardia	4	9	13
Ear and labyrinth disorders	Deafness	4	0	4
	Deafness unilateral	1	0	1
	Ear discomfort	0	4	4
	Ear pain	3	4	7
	Hyperacusis	2	0	2
	Hypoacusis	2	3	5
	Inner ear disorder	1	0	1
	Motion sickness	1	0	1
	Tinnitus	23	29	52
	Vertigo	16	15	31
	Vestibular disorder	1	0	1
Endocrine disorders	Basedow's disease	0	1	1
	Goitre	0	1	1
	Thyroid disorder	0	1	1
Eye disorders	Acute macular neuroretinopathy	2	0	2
	Altered visual depth perception	1	0	1
	Asthenopia	0	2	2
	Blepharitis	1	0	1
	Blindness	1	1	2
	Blindness unilateral	2	0	2
	Cataract	1	0	1
	Central serous chorioretinopathy	1	0	1
	Chorioretinopathy	1	0	1
	Diplopia	2	0	2
	Eye disorder	0	1	1
	Eye inflammation	0	1	1
	Eye irritation	0	1	1
	Eye movement disorder	1	0	1
	Eye pain	2	5	7
	Eye swelling	1	1	2
	Glaucoma	0	1	1
	Lacrimation increased	2	1	3
	Ocular hyperaemia	1	2	3
	Photophobia	2	0	2
	Retinal artery occlusion	1	0	1
	Swelling of eyelid	1	0	1
	Vision blurred	6	9	15
	Visual acuity reduced	3	0	3
	Visual impairment	5	6	11
Gastrointestinal disorders	Abdominal discomfort	3	3	6
	Abdominal distension	1	1	2
	Abdominal pain	20	3	23
	Abdominal pain lower	0	1	1
	Abdominal pain upper	6	9	15
	Aphthous ulcer	1	2	3
	Chapped lips	0	1	1

Constipation	1	0	1
Dental discomfort	1	0	1
Diarrhoea	19	10	29
Dry mouth	1	2	3
Dyspepsia	2	1	3
Dysphagia	3	0	3
Faeces discoloured	1	1	2
Flatulence	1	0	1
Frequent bowel movements	1	0	1
Gastrointestinal disorder	0	1	1
Gastrointestinal motility disorder	0	1	1
Gastrointestinal pain	1	0	1
Gingival bleeding	0	1	1
Glossodynia	0	1	1
Haematemesis	1	0	1
Hyperchlorhydria	1	0	1
Hypoaesthesia oral	1	2	3
Intestinal ischaemia	1	0	1
Lip swelling	1	1	2
Mesenteric vein thrombosis	1	0	1
Mouth swelling	1	0	1
Nausea	215	99	314
Odynophagia	0	1	1
Oesophageal discomfort	0	1	1
Oral discomfort	1	0	1
Oral pain	0	1	1
Palatal disorder	1	0	1
Pancreatitis	1	0	1
Pancreatitis acute	1	0	1
Retching	0	2	2
Small intestinal haemorrhage	1	0	1
Swollen tongue	1	0	1
Tongue coated	1	1	2
Vomiting	28	20	48
General disorders and administration site conditions			
Administration site pain	1	0	1
Adverse event	0	1	1
Application site pain	0	1	1
Asthenia	29	19	48
Axillary pain	2	0	2
Chest discomfort	14	8	22
Chest pain	21	12	33
Chills	326	121	447
Condition aggravated	4	1	5
Death	11	0	11
Decreased activity	2	0	2
Discomfort	3	4	7
Disease recurrence	2	0	2
Drug ineffective	1	0	1
Exercise tolerance decreased	1	1	2
Extensive swelling of vaccinated limb	18	13	31

Face oedema	1	0	1
Facial pain	0	2	2
Fatigue	388	232	620
Feeling abnormal	2	9	11
Feeling cold	7	8	15
Feeling hot	6	7	13
Feeling of body temperature change	5	6	11
Feeling of relaxation	0	1	1
Gait disturbance	7	6	13
Gait inability	0	2	2
General physical health deterioration	3	0	3
Hypothermia	1	0	1
Ill-defined disorder	0	1	1
Illness	2	9	11
Inflammation	2	1	3
Influenza like illness	44	28	72
Injection site bruising	2	0	2
Injection site discolouration	0	1	1
Injection site discomfort	1	0	1
Injection site erythema	3	4	7
Injection site haematoma	1	0	1
Injection site induration	0	2	2
Injection site mass	0	1	1
Injection site movement impairment	2	0	2
Injection site nodule	1	0	1
Injection site pain	19	29	48
Injection site pruritus	0	1	1
Injection site rash	1	0	1
Injection site reaction	152	73	225
Injection site swelling	4	2	6
Injection site warmth	0	2	2
Malaise	269	126	395
Medical device site joint erythema	0	1	1
Medical device site warmth	0	1	1
Mucosal disorder	0	1	1
Mucosal dryness	1	0	1
Multiple organ dysfunction syndrome	1	0	1
Oedema	1	0	1
Oedema peripheral	2	1	3
Pain	16	20	36
Peripheral swelling	7	9	16
Pre-existing condition improved	1	0	1
Pyrexia	347	201	548
Sense of oppression	4	1	5
Sluggishness	1	1	2
Sudden death	2	0	2
Swelling	3	0	3
Swelling face	0	1	1
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	6	0	6
	Vaccination site bruising	2	0	2
	Vaccination site pain	1	0	1
	Vaccination site swelling	1	0	1
Hepatobiliary disorders	Hepatic failure	1	0	1
	Hepatic pain	1	2	3
	Portal vein thrombosis	1	0	1
Immune system disorders	Allergy to arthropod bite	1	0	1
	Anaphylactic reaction	2	0	2
	Autoimmune disorder	4	0	4
	Hypersensitivity	5	7	12
	Immune system disorder	2	0	2
Infections and infestations	Appendicitis	1	0	1
	Asymptomatic COVID-19	1	0	1
	Breakthrough COVID-19	0	1	1
	Bronchitis	2	0	2
	COVID-19	30	15	45
	COVID-19 pneumonia	2	0	2
	Conjunctivitis	1	0	1
	Ear infection	0	2	2
	Encephalitis	1	0	1
	Epididymitis	1	0	1
	Fungal infection	1	0	1
	Genital herpes	1	1	2
	Genital ulcer syndrome	1	0	1
	Herpes ophthalmic	1	0	1
	Herpes simplex	0	1	1
	Herpes zoster	2	3	5
	Hordeolum	2	0	2
	Infection	1	0	1
	Influenza	1	1	2
	Injection site infection	1	0	1
	Meningitis viral	1	0	1
	Nasopharyngitis	4	15	19
	Oral herpes	0	2	2
	Oral infection	0	1	1
	Pharyngitis	1	0	1
	Pneumonia	3	1	4
	Pustule	0	1	1
	Rash pustular	0	1	1
	Rhinitis	0	1	1
	Septic shock	1	0	1
	Suspected COVID-19	2	3	5
	Tonsillitis	1	0	1
	Urinary tract infection	0	1	1
Injury, poisoning and procedural complications	Chillblains	1	0	1
	Contusion	0	5	5

	Exposure via breast milk	0	1	1
	Fall	6	1	7
	Inappropriate schedule of product	0	2	2
	Maternal exposure during breast feeding	0	1	1
	Metal poisoning	0	1	1
	Muscle injury	0	1	1
	Nasal injury	1	0	1
	Off label use	1	2	3
	Product administered to patient of	1	0	1
	Product administration error	0	1	1
Investigations	Blood creatine phosphokinase increased	1	0	1
	Blood glucose increased	1	0	1
	Blood pressure decreased	3	0	3
	Blood pressure increased	2	4	6
	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	2	8
	Heart rate decreased	1	0	1
	Heart rate increased	11	7	18
	Heart rate irregular	0	1	1
	Heparin-induced thrombocytopenia test	1	0	1
	Hormone level abnormal	0	2	2
	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
	Respiratory rate increased	0	1	1
	Reticulocyte count increased	1	0	1
	SARS-CoV-2 test positive	9	5	14
	Shift to the left	1	0	1
	Sperm concentration decreased	1	0	1
	Total lung capacity decreased	1	0	1
	Troponin abnormal	1	0	1
	Troponin increased	3	0	3
Weight decreased	2	0	2	
White blood cell count decreased	0	1	1	
Metabolism and nutrition disorders	Appetite disorder	1	0	1
	Decreased appetite	14	7	21
	Dehydration	3	1	4
	Fluid retention	0	1	1

Musculoskeletal and connective tissue disorders	Arthralgia	201	93	294
	Arthritis	2	0	2
	Arthropathy	1	0	1
	Axillary mass	0	1	1
	Back pain	15	18	33
	Bone pain	0	2	2
	Bursitis	2	0	2
	Epiphyseal disorder	1	0	1
	Groin pain	1	0	1
	Joint ankylosis	1	0	1
	Joint stiffness	3	1	4
	Limb discomfort	9	9	18
	Muscle atrophy	1	0	1
	Muscle spasms	12	8	20
		Muscle tightness	1	1
Muscular weakness		11	8	19
Musculoskeletal chest pain		2	1	3
Musculoskeletal discomfort		2	1	3
Musculoskeletal pain		2	0	2
Musculoskeletal stiffness		10	10	20
Myalgia		326	172	498
Neck pain		8	10	18
Neuropathic muscular atrophy		1	0	1
Nuchal rigidity		1	0	1
Pain in extremity		32	39	71
Pain in jaw		0	2	2
Periarthritis		1	0	1
Polymyalgia rheumatica		1	0	1
Temporomandibular joint syndrome		1	0	1
Tendon disorder		0	1	1
Tendon pain		1	0	1
Torticollis	1	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiocentric lymphoma	1	0	1
	Brain neoplasm benign	1	0	1
	Colon cancer stage IV	1	0	1
	Metastases to liver	1	0	1
Nervous system disorders	Ageusia	3	5	8
	Allodynia	1	0	1
	Altered state of consciousness	2	0	2
	Amnesia	1	1	2
	Anosmia	4	3	7
	Balance disorder	6	4	10
	Bell's palsy	1	0	1
	Burning sensation	4	3	7
	Carotid artery dissection	1	0	1
	Cerebral haematoma	1	0	1
	Cerebral haemorrhage	3	0	3
	Cerebral venous thrombosis	1	0	1
	Cerebrovascular accident	3	0	3
	Cognitive disorder	1	0	1

Disturbance in attention	3	5	8
Dizziness	36	35	71
Dizziness postural	1	0	1
Dysgeusia	2	8	10
Dyskinesia	1	0	1
Dysstasia	2	4	6
Electric shock sensation	2	1	3
Encephalomalacia	1	0	1
Facial paralysis	2	0	2
Facial paresis	1	0	1
Febrile convulsion	1	0	1
Guillain-Barre syndrome	4	0	4
Head discomfort	4	3	7
Headache	393	223	616
Hemianopia	1	0	1
Hemiparesis	1	0	1
Hemiplegia	2	0	2
Horner's syndrome	1	0	1
Hyperaesthesia	0	1	1
Hyperreflexia	1	0	1
Hypersomnia	2	5	7
Hypoaesthesia	6	13	19
Hypokinesia	1	0	1
Hypotonia	2	0	2
Ischaemic stroke	2	0	2
Loss of consciousness	8	0	8
Memory impairment	2	1	3
Mental impairment	2	1	3
Meralgia paraesthetica	1	0	1
Migraine	10	7	17
Miller Fisher syndrome	1	0	1
Monoplegia	1	0	1
Movement disorder	3	0	3
Multiple sclerosis	0	1	1
Muscle contractions involuntary	1	0	1
Narcolepsy	1	0	1
Nervous system disorder	6	2	8
Neuralgia	5	3	8
Neuralgic amyotrophy	2	0	2
Neuropathy peripheral	0	1	1
Ophthalmic migraine	1	0	1
Paraesthesia	22	22	44
Paralysis	1	0	1
Parosmia	0	4	4
Partial seizures	1	0	1
Presyncope	3	0	3
Psychomotor hyperactivity	1	0	1
Reduced facial expression	0	1	1
Restless legs syndrome	0	4	4
Sciatica	0	1	1

	Seizure	2	0	2
	Sensory disturbance	0	4	4
	Sensory loss	2	3	5
	Somnolence	4	5	9
	Speech disorder	2	2	4
	Spinal cord disorder	1	0	1
	Superior sagittal sinus thrombosis	1	0	1
	Syncope	13	0	13
	Taste disorder	1	1	2
	Tremor	11	14	25
	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	Affect lability	1	0	1
	Affective disorder	1	0	1
	Aggression	1	0	1
	Algophobia	0	1	1
	Anxiety	2	3	5
	Apathy	0	1	1
	Confusional state	4	2	6
	Conversion disorder	1	0	1
	Delirium	2	0	2
	Depersonalisation/derealisation disorder	1	0	1
	Depressed mood	1	0	1
	Depression	1	0	1
	Disorganised speech	0	1	1
	Disorientation	2	0	2
	Dissociation	1	0	1
	Emotional disorder	0	1	1
	Emotional distress	0	1	1
	Hallucination	3	0	3
	Head banging	1	0	1
	Hyposomnia	1	0	1
	Insomnia	12	9	21
	Irritability	0	1	1
	Libido decreased	0	1	1
	Listless	0	1	1
	Mental fatigue	0	1	1
	Mood altered	0	1	1
	Mood swings	1	0	1
	Nightmare	0	1	1
	Paramnesia	0	1	1
	Poor quality sleep	4	3	7
	Restlessness	1	0	1
	Sleep disorder	5	2	7
	Thinking abnormal	0	1	1
Renal and urinary disorders	Acute kidney injury	3	0	3
	Bladder disorder	1	0	1
	Cystitis noninfective	0	2	2

	Glomerulonephritis membranous	1	0	1
	Glomerulonephritis minimal lesion	1	0	1
	Haematuria	0	1	1
	Nephrolithiasis	1	0	1
	Nephrotic syndrome	1	0	1
	Pollakiuria	1	0	1
	Renal disorder	2	0	2
	Renal infarct	1	0	1
	Renal pain	2	3	5
	Renal vein thrombosis	1	0	1
	Urinary incontinence	0	1	1
	Urinary retention	1	0	1
	Urine abnormality	1	1	2
Reproductive system and breast disorders	Adnexa uteri pain	0	1	1
	Amenorrhoea	4	21	25
	Breast pain	0	3	3
	Breast swelling	1	1	2
	Dysmenorrhoea	4	4	8
	Endometriosis	0	1	1
	Erectile dysfunction	1	0	1
	Heavy menstrual bleeding	9	12	21
	Hypomenorrhoea	1	1	2
	Intermenstrual bleeding	2	7	9
	Menometrorrhagia	1	3	4
	Menstrual disorder	7	13	20
	Menstruation delayed	1	5	6
	Menstruation irregular	7	13	20
	Oligomenorrhoea	1	5	6
	Ovarian cyst	1	1	2
	Pelvic pain	2	0	2
	Polymenorrhoea	4	5	9
	Postmenopausal haemorrhage	4	0	4
	Premenstrual pain	0	1	1
	Testicular pain	2	1	3
	Testicular swelling	1	0	1
	Uterine cyst	1	0	1
	Uterine spasm	0	1	1
	Vaginal haemorrhage	2	4	6
	Vaginal odour	0	1	1
	Vulvovaginal inflammation	1	0	1
Respiratory, thoracic and mediastinal disorders	Aphonia	0	1	1
	Asphyxia	1	0	1
	Asthma	0	1	1
	Asthmatic crisis	1	0	1
	Choking sensation	1	0	1
	Cough	8	10	18
	Dysphonia	1	0	1
	Dyspnoea	25	26	51
	Dyspnoea at rest	1	0	1
	Dyspnoea exertional	1	0	1

Epistaxis	2	6	8
Haemoptysis	0	1	1
Hyperventilation	3	2	5
Lung disorder	2	0	2
Nasal congestion	2	0	2
Nasal obstruction	1	1	2
Oropharyngeal discomfort	1	0	1
Oropharyngeal pain	5	7	12
Paranasal sinus discomfort	0	1	1
Pharyngeal oedema	1	0	1
Pharyngeal swelling	2	0	2
Pleural effusion	2	0	2
Pleurisy	1	1	2
Pneumothorax	1	0	1
Productive cough	0	1	1
Pulmonary embolism	8	0	8
Pulmonary infarction	1	0	1
Pulmonary oedema	2	0	2
Pulmonary pain	2	0	2
Respiratory arrest	1	0	1
Respiratory depth decreased	0	1	1
Respiratory disorder	4	5	9
Respiratory distress	2	0	2
Respiratory failure	4	0	4
Rhinorrhoea	5	4	9
Sinus pain	0	1	1
Sneezing	4	0	4
Throat irritation	0	1	1
Tracheal disorder	1	0	1
Vocal cord disorder	1	0	1
Vocal cord dysfunction	1	0	1
Wheezing	0	1	1
Yawning	1	0	1
Skin and subcutaneous tissue disorders			
Acne	2	0	2
Blood blister	1	0	1
Cold sweat	0	2	2
Dermatitis allergic	0	1	1
Dry skin	1	0	1
Ecchymosis	1	2	3
Eczema	0	1	1
Erythema	3	6	9
Erythema multiforme	1	0	1
Henoch-Schonlein purpura	1	0	1
Hyperhidrosis	25	12	37
Night sweats	1	1	2
Pain of skin	0	2	2
Papule	0	1	1
Petechiae	3	2	5
Piloerection	0	1	1
Pruritus	4	5	9

	Psoriasis	3	1	4
	Purpura	1	1	2
	Pyoderma gangrenosum	1	0	1
	Rash	9	2	11
	Rash erythematous	1	3	4
	Rash macular	6	3	9
	Rash papular	1	0	1
	Rash pruritic	3	1	4
	Sensitive skin	3	0	3
	Skin burning sensation	1	2	3
	Skin discolouration	0	1	1
	Skin disorder	52	28	80
	Skin mass	0	1	1
	Skin odour abnormal	2	0	2
	Skin reaction	0	1	1
	Urticaria	6	0	6
Social circumstances	Bedridden	0	2	2
	Housebound	1	0	1
	Impaired driving ability	0	2	2
	Impaired work ability	3	5	8
	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	3	1	4
	COVID-19 immunisation	6	4	10
	Pacemaker generated rhythm	1	0	1
	Thrombosis prophylaxis	0	1	1
Vascular disorders	Cyanosis	2	0	2
	Deep vein thrombosis	5	0	5
	Haematoma	1	2	3
	Haemorrhage	1	0	1
	Hot flush	7	4	11
	Hypertension	6	4	10
	Hypertensive crisis	1	0	1
	Hypotension	5	3	8
	Hypovolaemic shock	1	0	1
	Microangiopathy	1	0	1
	Orthostatic hypotension	0	1	1
	Pallor	2	1	3
	Peripheral coldness	3	1	4
	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	2	2
	Vasculitis	1	0	1
	Vasodilatation	0	2	2
	Vein discolouration	1	0	1

	Vein disorder	1	0	1
	Venous occlusion	1	0	1
Total		4125	2494	6.619