

## Summary Tabulation 21-09-2021

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

Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Coagulopathy	8	0	8
	Disseminated intravascular coagulation	1	0	1
	Haemolysis	1	0	1
	Haemolytic anaemia	1	0	1
	Hypofibrinogenaemia	1	0	1
	Lymph node pain	0	1	1
	Lymphadenopathy	1	2	3
	Red blood cell abnormality	1	0	1
	Splenic infarction	1	0	1
	Splenic vein thrombosis	1	0	1
	Thrombocytopenia	3	0	3
Cardiac disorders	Acute myocardial infarction	3	0	3
	Angina pectoris	2	0	2
	Arrhythmia	2	0	2
	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	8	5	13
	Pericarditis	1	1	2
	Tachycardia	2	4	6
Ear and labyrinth disorders	Deafness	3	1	4
	Ear discomfort	0	1	1
	Ear pain	2	2	4
	Hyperacusis	2	0	2
	Hypoacusis	2	0	2
	Motion sickness	1	0	1
	Tinnitus	12	5	17
	Vertigo	9	9	18

	Vestibular disorder	1	0	1	
Eye disorders	Acute macular outer retinopathy	1	1	2	
	Asthenopia	0	1	1	
	Blindness unilateral	1	0	1	
	Diplopia	1	0	1	
	Eye movement disorder	1	0	1	
	Eye pain	1	1	2	
	Eye swelling	1	0	1	
	Lacrimation increased	2	0	2	
	Ocular hyperaemia	0	1	1	
	Photophobia	2	0	2	
	Vision blurred	3	5	8	
	Visual acuity reduced	2	0	2	
	Visual impairment	4	2	6	
	Gastrointestinal disorders	Abdominal discomfort	2	0	2
Abdominal pain		14	1	15	
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		13	3	16	
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	
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		164	44	208	
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		21	11	32	
General disorders and administration site conditions		Administration site pain	1	0	1
		Application site pain	0	1	1
	Asthenia	17	11	28	
	Chest discomfort	10	2	12	
	Chest pain	10	3	13	
	Chills	245	44	289	

	Condition aggravated	2	1	3
	Death	10	0	10
	Discomfort	3	3	6
	Disease recurrence	1	0	1
	Extensive swelling of vaccinated limb	12	1	13
	Face oedema	1	0	1
	Fatigue	283	81	364
	Feeling abnormal	1	2	3
	Feeling cold	6	3	9
	Feeling hot	4	7	11
	Feeling of body temperature change	3	3	6
	Feeling of relaxation	0	1	1
	Gait disturbance	5	4	9
	General physical health deterioration	2	0	2
	Illness	2	8	10
	Inflammation	1	0	1
	Influenza like illness	29	15	44
	Injection site bruising	2	0	2
	Injection site erythema	2	2	4
	Injection site haematoma	1	0	1
	Injection site mass	0	1	1
	Injection site movement impairment	2	0	2
	Injection site pain	9	16	25
	Injection site pruritus	0	1	1
	Injection site rash	1	0	1
	Injection site reaction	100	14	114
	Injection site swelling	2	1	3
	Malaise	208	36	244
	Multiple organ dysfunction syndrome	1	0	1
	Oedema	1	0	1
	Oedema peripheral	2	0	2
	Pain	9	10	19
	Peripheral swelling	2	4	6
	Pre-existing condition improved	1	0	1
	Pyrexia	271	94	365
	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	6	0	6
	Thirst	0	1	1
	Thirst decreased	1	0	1
	Vaccination failure	1	0	1
	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	2	0	2
	Hypersensitivity	3	3	6
	Immune system disorder	1	0	1
Infections and infestations	Appendicitis	1	0	1
	COVID-19	6	5	11
	COVID-19 pneumonia	1	0	1
	Ear infection	0	1	1
	Genital herpes	1	1	2
	Herpes ophthalmic	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	7	8
	Oral infection	0	1	1
	Pneumonia	1	0	1
	Septic shock	1	0	1
	Suspected COVID-19	1	0	1
	Tonsillitis	1	0	1
	Injury, poisoning and procedural complications	Contusion	0	3
Fall		4	0	4
Muscle injury		0	1	1
Nasal injury		1	0	1
Off label use		1	0	1
Product administered to patient of		1	0	1
Product administration error		0	1	1
Investigations	Blood glucose increased	1	0	1
	Blood pressure decreased	2	0	2
	Blood pressure increased	0	2	2
	Body temperature increased	1	2	3
	C-reactive protein increased	3	1	4
	Fibrin D dimer increased	4	0	4
	Heart rate increased	9	2	11
	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	0	1	1
	PCO2 decreased	1	0	1
	Prothrombin time shortened	1	1	2
	SARS-CoV-2 test positive	1	2	3
	Troponin abnormal	1	0	1
	Troponin increased	2	0	2
	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	135	22	157
	Back pain	13	7	20
	Bone pain	0	1	1
	Bursitis	2	0	2
	Groin pain	1	0	1
	Limb discomfort	7	4	11
	Muscle spasms	6	4	10
	Muscle tightness	1	1	2
	Muscular weakness	4	6	10
	Musculoskeletal discomfort	1	0	1
	Musculoskeletal stiffness	7	8	15
	Myalgia	238	58	296
	Neck pain	4	5	9
	Nuchal rigidity	1	0	1
	Pain in extremity	13	14	27
	Pain in jaw	0	1	1
	Periarthritis	1	0	1
	Polymyalgia rheumatica	1	0	1
	Torticollis	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiocentric lymphoma	1	0	1
Nervous system disorders	Ageusia	1	1	2
	Allodynia	1	0	1
	Altered state of consciousness	1	0	1
	Anosmia	1	1	2
	Balance disorder	2	2	4
	Bell's palsy	1	0	1
	Burning sensation	1	0	1
	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	0	1
	Dizziness	32	21	53
	Dizziness postural	1	0	1
	Dysgeusia	1	6	7
	Dyskinesia	1	0	1
	Dysstasia	2	2	4
	Electric shock sensation	2	1	3
	Febrile convulsion	1	0	1
	Head discomfort	3	1	4
	Headache	289	90	379
	Hemiparesis	1	0	1
	Hemiplegia	1	0	1
	Hyperreflexia	0	1	1
	Hypersomnia	0	1	1

	Hypoaesthesia	3	1	4
	Hypokinesia	1	0	1
	Hypotonia	1	0	1
	Ischaemic stroke	1	0	1
	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
	Narcolepsy	1	0	1
	Nervous system disorder	5	0	5
	Neuralgia	1	1	2
	Paraesthesia	10	7	17
	Partial seizures	1	0	1
	Presyncope	3	0	3
	Psychomotor hyperactivity	1	0	1
	Restless legs syndrome	0	1	1
	Seizure	1	0	1
	Sensory disturbance	0	2	2
	Sensory loss	2	2	4
	Somnolence	2	1	3
	Speech disorder	0	1	1
	Superior sagittal sinus thrombosis	1	0	1
	Syncope	5	1	6
	Taste disorder	1	0	1
	Tremor	7	7	14
	Trigeminal nerve disorder	0	1	1
Pregnancy, puerperium and perinatal conditions	Foetal death	2	0	2
	High foetal head	1	0	1
Psychiatric disorders	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	0	1
	Emotional distress	0	1	1
	Hallucination	1	0	1
	Head banging	1	0	1
	Insomnia	9	4	13
	Irritability	0	1	1
	Mood altered	0	1	1
	Mood swings	1	0	1
	Nightmare	0	1	1
	Poor quality sleep	2	3	5
	Restlessness	1	0	1
	Sleep disorder	3	0	3
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	1	2
	Dysmenorrhoea	1	1	2
	Menstrual disorder	1	0	1
	Menstruation delayed	1	3	4
	Menstruation irregular	1	1	2
	Pelvic pain	1	0	1
	Testicular pain	1	0	1
	Testicular swelling	1	0	1
	Vaginal haemorrhage	2	0	2
Respiratory, thoracic and mediastinal disorders	Asphyxia	1	0	1
	Cough	4	5	9
	Dyspnoea	12	10	22
	Epistaxis	0	2	2
	Haemoptysis	0	1	1
	Hyperventilation	2	0	2
	Lung disorder	1	0	1
	Nasal obstruction	0	1	1
	Oropharyngeal pain	4	1	5
	Paranasal sinus discomfort	0	1	1
	Pharyngeal swelling	2	0	2
	Pneumothorax	1	0	1
	Pulmonary embolism	5	0	5
	Pulmonary infarction	1	0	1
	Pulmonary oedema	1	0	1
	Respiratory disorder	1	2	3
	Respiratory distress	2	1	3
	Respiratory failure	3	0	3
	Rhinorrhoea	3	0	3
	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	1	1
	Erythema	0	3	3
	Erythema multiforme	1	0	1
	Henoch-Schonlein purpura	1	0	1
	Hyperhidrosis	20	3	23
	Night sweats	1	1	2
	Pain of skin	0	1	1
	Petechiae	3	0	3

	Piloerection	0	1	1
	Pruritus	1	1	2
	Psoriasis	1	0	1
	Purpura	1	0	1
	Pyoderma gangrenosum	1	0	1
	Rash	5	1	6
	Rash macular	4	0	4
	Rash pruritic	2	0	2
	Sensitive skin	2	0	2
	Skin burning sensation	1	0	1
	Skin disorder	32	3	35
	Skin odour abnormal	2	0	2
	Skin reaction	0	1	1
	Urticaria	2	0	2
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
	Sight disability	1	0	1
Surgical and medical procedures	Bed rest	1	1	2
	Plasmapheresis	1	0	1
Vascular disorders	Cyanosis	2	0	2
	Deep vein thrombosis	2	0	2
	Haematoma	2	1	3
	Haemorrhage	1	0	1
	Hot flush	5	0	5
	Hypertension	3	2	5
	Hypotension	3	2	5
	Hypovolaemic shock	1	0	1
	Microangiopathy	1	0	1
	Pallor	2	1	3
	Peripheral coldness	3	0	3
	Phlebitis	1	1	2
	Raynaud's phenomenon	1	0	1
	Shock	2	0	2
	Thrombophlebitis superficial	0	1	1
	Thrombosis	5	0	5
	Vasodilatation	0	1	1
	Vein discolouration	1	0	1
	Venous occlusion	1	0	1
<b>Total</b>		<b>2787</b>	<b>902</b>	<b>3 689</b>