

## Summary Tabulation 13.07.2021

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	5	0	5
	Disseminated intravascular coagulation	1	0	1
	Hypofibrinogenaemia	1	0	1
	Lymphadenopathy	0	1	1
	Splenic infarction	1	0	1
	Splenic vein thrombosis	1	0	1
	Thrombocytopenia	2	0	2
Cardiac disorders	Acute myocardial infarction	2	0	2
	Angina pectoris	1	0	1
	Arrhythmia	1	0	1
	Cardiac arrest	1	0	1
	Cardiac failure	1	0	1
	Cardio-respiratory arrest	1	0	1
	Cardiovascular disorder	6	0	6
	Myocardial infarction	1	0	1
	Myocarditis	1	0	1
	Palpitations	3	2	5
	Pericarditis	1	0	1
	Tachycardia	1	2	3
	Ear and labyrinth disorders	Deafness	1	1
Ear discomfort		0	1	1
Hyperacusis		1	0	1
Motion sickness		1	0	1
Tinnitus		1	0	1
Vertigo		1	1	2
Eye disorders	Asthenopia	0	1	1
	Eye pain	1	0	1
	Eye swelling	1	0	1
	Photophobia	1	0	1
	Vision blurred	1	0	1
	Visual acuity reduced	1	0	1
	Visual impairment	2	2	4
Gastrointestinal disorders	Abdominal pain	10	0	10
	Abdominal pain upper	1	1	2
	Aphthous ulcer	1	0	1
	Chapped lips	0	1	1
	Constipation	1	0	1

	Diarrhoea	10	0	10
	Dry mouth	0	1	1
	Dysphagia	1	0	1
	Faeces discoloured	1	0	1
	Frequent bowel movements	2	0	2
	Intestinal ischaemia	2	0	2
	Lip swelling	1	1	2
	Mesenteric vein thrombosis	1	0	1
	Mouth swelling	1	0	1
	Nausea	89	15	104
	Palatal disorder	1	0	1
	Vomiting	6	4	10
General disorders and administration site conditions	Application site pain	0	1	1
	Asthenia	7	1	8
	Chest discomfort	4	0	4
	Chest pain	5	1	6
	Chills	138	11	149
	Death	10	0	10
	Discomfort	0	1	1
	Disease recurrence	1	0	1
	Extensive swelling of vaccinated limb	6	0	6
	Face oedema	1	0	1
	Fatigue	154	29	183
	Feeling abnormal	1	1	2
	Feeling cold	1	1	2
	Feeling hot	2	5	7
	Feeling of body temperature change	1	3	4
	Gait disturbance	3	0	3
	General physical health deterioration	2	0	2
	Illness	0	3	3
	Inflammation	1	0	1
	Influenza like illness	19	12	31
	Injection site erythema	1	2	3
	Injection site mass	0	1	1
	Injection site pain	2	11	13
	Injection site pruritus	0	1	1
	Injection site reaction	51	4	55
	Injection site swelling	0	1	1
	Malaise	111	14	125
	Multiple organ dysfunction syndrome	1	0	1
	Pain	4	4	8
	Peripheral swelling	2	1	3
	Pyrexia	151	39	190
	Sense of oppression	2	0	2
	Sluggishness	1	1	2
	Sudden death	2	0	2
	Swelling	2	0	2
	Therapeutic response unexpected	0	1	1
	Therapy non-responder	3	0	3
	Thirst	0	1	1

	Vaccination site bruising	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
	Hypersensitivity	0	2	2
Infections and infestations	COVID-19	1	0	1
	Herpes ophthalmic	0	1	1
	Hordeolum	1	0	1
	Infection	1	0	1
	Influenza	1	1	2
	Injection site infection	1	0	1
	Nasopharyngitis	0	5	5
	Oral infection	0	1	1
	Septic shock	1	0	1
Injury, poisoning and procedural complications	Contusion	0	1	1
	Fall	2	0	2
	Muscle injury	0	1	1
	Product administration error	0	1	1
Investigations	Blood glucose increased	1	0	1
	Body temperature increased	0	2	2
	C-reactive protein increased	2	1	3
	Fibrin D dimer increased	2	0	2
	Heart rate increased	6	1	7
	Lymphocyte count decreased	0	1	1
	Neutrophil count increased	0	1	1
	PCO2 decreased	1	0	1
	Prothrombin time shortened	1	1	2
	Troponin increased	1	0	1
	White blood cell count decreased	0	1	1
Metabolism and nutrition disorders	Decreased appetite	4	0	4
	Dehydration	1	0	1
	Fluid retention	0	1	1
Musculoskeletal and connective tissue disorders	Arthralgia	82	5	87
	Back pain	4	2	6
	Groin pain	1	0	1
	Limb discomfort	2	2	4
	Muscle spasms	3	2	5
	Muscle tightness	1	0	1
	Muscular weakness	1	4	5
	Musculoskeletal discomfort	1	0	1
	Musculoskeletal stiffness	5	8	13
	Myalgia	138	24	162
	Neck pain	2	3	5
	Nuchal rigidity	1	0	1
	Pain in extremity	5	9	14
	Pain in jaw	0	1	1
	Periarthritis	1	0	1
Torticollis	1	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiocentric lymphoma	1	0	1

Nervous system disorders	Altered state of consciousness	1	0	1
	Balance disorder	2	0	2
	Cerebral haematoma	1	0	1
	Cerebral haemorrhage	3	0	3
	Cerebral venous thrombosis	1	0	1
	Cerebrovascular accident	2	0	2
	Dizziness	9	8	17
	Dysgeusia	0	1	1
	Dyskinesia	1	0	1
	Dysstasia	1	0	1
	Electric shock sensation	1	1	2
	Febrile convulsion	1	0	1
	Head discomfort	2	1	3
	Headache	162	40	202
	Hemiplegia	1	0	1
	Hypersomnia	0	1	1
	Hypoaesthesia	2	0	2
	Hypokinesia	1	0	1
	Loss of consciousness	3	0	3
	Migraine	2	2	4
	Narcolepsy	1	0	1
	Nervous system disorder	3	0	3
	Neuralgia	1	0	1
	Paraesthesia	4	1	5
	Partial seizures	1	0	1
	Presyncope	2	0	2
	Psychomotor hyperactivity	1	0	1
	Restless legs syndrome	0	1	1
	Somnolence	2	0	2
	Superior sagittal sinus thrombosis	1	0	1
	Syncope	3	0	3
Taste disorder	1	0	1	
Tremor	2	3	5	
Trigeminal nerve disorder	0	1	1	
Pregnancy, puerperium and perinatal conditions	Foetal death	2	0	2
	High foetal head	1	0	1
Psychiatric disorders	Confusional state	1	1	2
	Conversion disorder	1	0	1
	Insomnia	5	2	7
	Nightmare	0	1	1
	Poor quality sleep	0	2	2
	Sleep disorder	1	0	1
Renal and urinary disorders	Acute kidney injury	1	0	1
	Pollakiuria	1	0	1
	Renal infarct	1	0	1
	Renal pain	1	1	2
	Renal vein thrombosis	1	0	1
Reproductive system and breast disorders	Menstruation delayed	0	1	1
	Menstruation irregular	0	1	1
	Vaginal haemorrhage	1	0	1

Respiratory, thoracic and mediastinal disorders	Cough	3	2	5
	Dyspnoea	3	2	5
	Haemoptysis	0	1	1
	Hyperventilation	2	0	2
	Nasal obstruction	0	1	1
	Oropharyngeal pain	2	0	2
	Paranasal sinus discomfort	0	1	1
	Pharyngeal swelling	1	0	1
	Pneumothorax	1	0	1
	Pulmonary embolism	2	0	2
	Pulmonary infarction	1	0	1
	Pulmonary oedema	1	0	1
	Respiratory disorder	1	0	1
	Rhinorrhoea	2	0	2
	Throat irritation	0	1	1
Skin and subcutaneous tissue disorders	Blood blister	1	0	1
	Dry skin	1	0	1
	Erythema	0	2	2
	Hyperhidrosis	4	2	6
	Night sweats	1	1	2
	Petechiae	1	0	1
	Piloerection	0	1	1
	Pruritus	1	0	1
	Pyoderma gangrenosum	1	0	1
	Rash	2	1	3
	Rash macular	2	0	2
	Rash pruritic	1	0	1
	Sensitive skin	1	0	1
	Skin burning sensation	1	0	1
	Skin disorder	14	1	15
Urticaria	1	0	1	
Social circumstances	Impaired work ability	0	1	1
	Loss of personal independence in daily activities	1	0	1
Vascular disorders	Cyanosis	2	0	2
	Deep vein thrombosis	2	0	2
	Haematoma	0	1	1
	Hot flush	1	0	1
	Hypertension	1	0	1
	Hypotension	1	0	1
	Hypovolaemic shock	1	0	1
	Pallor	1	1	2
	Peripheral coldness	1	0	1
	Phlebitis	1	0	1
	Raynaud's phenomenon	1	0	1
	Shock	1	0	1
	Thrombophlebitis superficial	0	1	1
	Thrombosis	2	0	2
	Vasodilatation	0	1	1
	Vein discolouration	1	0	1
Venous occlusion	1	0	1	

<b>Total</b>		<b>1445</b>	<b>356</b>	<b>1.801</b>
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