

Summary Tabulation 25.01.2022

[Interprétation correcte des données : lire ici](#)

[Correcte interpretatie van de gegevens : lees hier](#)

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	8	4	12
	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		2	0	2
Arrhythmia		4	1	5
Arteriospasm coronary		0	1	1
Cardiac arrest		2	0	2
Cardiac discomfort		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		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	10	12	22
	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
	Retinal detachment	1	0	1
	Swelling of eyelid	1	0	1
	Vision blurred	5	7	12
	Visual acuity reduced	3	0	3
	Visual impairment	4	3	7
Gastrointestinal disorders	Abdominal discomfort	3	1	4
	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	16	7	23
	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
Gastrointestinal pain	1	0	1
Haematemesis	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	199	64	263
Odynophagia	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
Small intestinal haemorrhage	1	0	1
Swollen tongue	1	0	1
Tongue coated	1	1	2
Vomiting	25	16	41
General disorders and administration site conditions			
Administration site pain	1	0	1
Application site pain	0	1	1
Asthenia	26	14	40
Axillary pain	1	0	1
Chest discomfort	15	2	17
Chest pain	18	8	26
Chills	303	71	374
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	16	5	21
Face oedema	1	0	1
Facial pain	0	1	1
Fatigue	351	145	496
Feeling abnormal	1	7	8
Feeling cold	7	6	13
Feeling hot	6	7	13
Feeling of body temperature change	4	5	9
Feeling of relaxation	0	1	1
Gait disturbance	6	5	11

	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	41	24	65
	Injection site bruising	2	0	2
	Injection site discomfort	1	0	1
	Injection site erythema	3	3	6
	Injection site haematoma	1	0	1
	Injection site induration	0	1	1
	Injection site inflammation	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	27	44
	Injection site pruritus	0	1	1
	Injection site rash	1	0	1
	Injection site reaction	138	27	165
	Injection site swelling	3	1	4
	Injection site warmth	0	2	2
	Malaise	247	65	312
	Multiple organ dysfunction syndrome	1	0	1
	Oedema	1	0	1
	Oedema peripheral	2	0	2
	Pain	14	15	29
	Peripheral swelling	4	5	9
	Pre-existing condition improved	1	0	1
	Pyrexia	324	136	460
	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	5	0	5
	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	2	0	2
	Autoimmune disorder	4	0	4
	Hypersensitivity	5	5	10

	Immune system disorder	1	0	1
Infections and infestations	Appendicitis	1	0	1
	Bronchitis	2	0	2
	COVID-19	29	11	40
	COVID-19 pneumonia	2	0	2
	Conjunctivitis	1	0	1
	Ear infection	0	2	2
	Encephalitis	0	1	1
	Fungal infection	1	0	1
	Genital herpes	1	1	2
	Genital ulcer syndrome	1	0	1
	Herpes ophthalmic	0	1	1
	Herpes simplex	0	1	1
	Herpes zoster	2	2	4
	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	12	15
	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	3	4
	Tonsillitis	1	0	1
Urinary tract infection	0	1	1	
Injury, poisoning and procedural complications	Contusion	0	5	5
	Exposure via breast milk	0	1	1
	Fall	6	1	7
	Inappropriate schedule of product administration	0	1	1
	Muscle injury	0	1	1
	Nasal injury	1	0	1
	Off label use	1	1	2
	Product administered to patient of inappropriate age	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	0	2	2
	Body temperature increased	1	3	4
	C-reactive protein increased	5	2	7
	Electrocardiogram repolarisation abnormality	1	0	1
	Eosinophil count increased	0	1	1

Fibrin D dimer increased	6	1	7
Heart rate increased	11	4	15
Heparin-induced thrombocytopenia test positive	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	9	5	14
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	7	20
Dehydration	2	1	3
Fluid retention	0	1	1
Musculoskeletal and connective tissue disorders			
Arthralgia	182	46	228
Arthritis	2	0	2
Arthropathy	1	0	1
Back pain	13	11	24
Bone pain	0	2	2
Bursitis	2	0	2
Groin pain	1	0	1
Intervertebral disc protrusion	1	0	1
Joint ankylosis	1	0	1
Joint stiffness	3	0	3
Limb discomfort	9	5	14
Muscle atrophy	1	0	1
Muscle spasms	8	7	15
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	299	97	396	
	Neck pain	6	5	11	
	Neuropathic muscular atrophy	1	0	1	
	Nuchal rigidity	1	0	1	
	Osteonecrosis	1	0	1	
	Pain in extremity	25	24	49	
	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	
	Amnesia	1	0	1	
	Anosmia	2	1	3	
	Balance disorder	5	3	8	
	Bell's palsy	1	0	1	
	Burning sensation	3	3	6	
	Carotid artery dissection	0	1	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	4	5	
	Dizziness	35	24	59	
	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
		Facial paresis	1	0	1
		Febrile convulsion	1	0	1
		Guillain-Barre syndrome	3	0	3
Head discomfort		3	2	5	
Headache		361	138	499	
Hemiparesis		1	0	1	
Hemiplegia		1	0	1	
Horner's syndrome		0	1	1	
Hyperaesthesia		0	1	1	

Hyperreflexia	0	1	1
Hypersomnia	2	4	6
Hypoaesthesia	5	3	8
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	8	3	11
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	5	1	6
Neuralgia	5	3	8
Neuralgic amyotrophy	2	0	2
Ophthalmic migraine	1	0	1
Paraesthesia	19	13	32
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	3	5
Speech disorder	2	2	4
Superior sagittal sinus thrombosis	1	0	1
Syncope	9	1	10
Taste disorder	1	1	2
Tremor	10	11	21
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

	Delirium	0	1	1
	Depersonalisation/derealisation disorder	1	0	1
	Depressed mood	1	0	1
	Depression	1	0	1
	Disorientation	1	1	2
	Dissociation	1	0	1
	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
	Cystitis noninfective	0	1	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 incontinence	0	1	1
	Urinary retention	1	0	1
	Urine abnormality	1	1	2
Reproductive system and breast disorders	Amenorrhoea	2	13	15
	Breast pain	0	3	3
	Breast swelling	0	1	1
	Dysmenorrhoea	3	3	6
	Heavy menstrual bleeding	6	9	15
	Hypomenorrhoea	1	1	2
	Intermenstrual bleeding	2	6	8
	Menometrorrhagia	1	2	3
	Menstrual disorder	6	11	17
	Menstruation delayed	1	4	5
	Menstruation irregular	6	10	16
	Oligomenorrhoea	1	5	6

	Pelvic pain	1	0	1
	Polymenorrhoea	4	4	8
	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
	Vulvovaginal inflammation	1	0	1
Respiratory, thoracic and mediastinal disorders	Aphonia	0	1	1
	Asphyxia	1	0	1
	Asthmatic crisis	1	0	1
	Cough	7	9	16
	Dyspnoea	18	20	38
	Dyspnoea at rest	1	0	1
	Dyspnoea exertional	1	0	1
	Epistaxis	1	6	7
	Haemoptysis	0	1	1
	Hyperventilation	3	0	3
	Lung disorder	1	0	1
	Nasal congestion	2	1	3
	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	6	0	6
	Pulmonary infarction	1	0	1
	Pulmonary oedema	2	0	2
	Pulmonary pain	0	1	1
	Respiratory arrest	1	0	1
	Respiratory disorder	4	3	7
	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
	Cold sweat	0	1	1
	Dry skin	1	0	1
	Ecchymosis	0	2	2

	Erythema	2	5	7
	Erythema multiforme	1	0	1
	Henoch-Schonlein purpura	1	0	1
	Hyperhidrosis	22	10	32
	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	43	11	54
	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	1	5	6
	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
	COVID-19 immunisation	1	0	1
	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	5	3	8
	Hypertensive crisis	1	0	1
	Hypotension	3	4	7
	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	1	1
Vasculitis	1	0	1
Vasodilatation	0	1	1
Vein discolouration	1	0	1
Venous occlusion	1	0	1
Venous thrombosis limb	1	0	1
Total	3666	1585	5.251