

Summary Tabulation 23.08.2022

[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
	Immune thrombocytopenia	1	0	1
	Increased tendency to bruise	1	2	3
	Lymph node pain	0	3	3
	Lymphadenopathy	10	14	24
	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	6	0	6
	Arrhythmia	5	0	5
	Arteriospasm coronary	1	0	1
	Cardiac arrest	2	0	2
	Cardiac discomfort	2	4	6
	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	3	14
	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	16	19	35
	Pericarditis	4	0	4
	Sinus tachycardia	0	1	1
	Tachycardia	4	11	15
Ear and labyrinth disorders	Deafness	4	0	4
	Deafness unilateral	1	0	1
	Ear discomfort	1	4	5
	Ear pain	5	4	9
	Hyperacusis	2	0	2
	Hypoacusis	2	3	5
	Inner ear disorder	1	0	1
	Motion sickness	1	0	1
	Tinnitus	27	31	58
	Vertigo	18	18	36
	Vestibular disorder	1	0	1
Endocrine disorders	Basedow's disease	0	1	1
	Diabetes insipidus	1	0	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	1	3	4
	Blepharitis	1	0	1
	Blindness	2	0	2
	Blindness transient	1	0	1
	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	1	0	1
	Eye inflammation	0	1	1
	Eye irritation	0	1	1
	Eye movement disorder	1	1	2
	Eye pain	2	6	8
	Eye swelling	1	1	2
	Glaucoma	1	0	1
	Lacrimation increased	2	1	3
	Mydriasis	1	0	1
	Ocular hyperaemia	2	1	3
	Photophobia	2	0	2
	Retinal artery occlusion	1	0	1
	Swelling of eyelid	1	0	1
	Vision blurred	9	13	22
	Visual acuity reduced	3	0	3
	Visual impairment	6	8	14
Gastrointestinal disorders	Abdominal discomfort	3	5	8
	Abdominal distension	1	3	4

Abdominal pain	23	6	29
Abdominal pain lower	1	1	2
Abdominal pain upper	6	10	16
Aphthous ulcer	2	2	4
Chapped lips	0	1	1
Constipation	1	0	1
Dental discomfort	1	0	1
Diarrhoea	21	16	37
Dry mouth	1	2	3
Dyspepsia	2	3	5
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	1	1	2
Gastrointestinal pain	1	0	1
Gingival bleeding	0	1	1
Gingival discomfort	1	0	1
Glossodynia	0	2	2
Haematemesis	1	0	1
Haemorrhoids	0	1	1
Hyperchlorhydria	1	0	1
Hypoaesthesia oral	2	3	5
Intestinal ischaemia	1	0	1
Lip swelling	1	2	3
Mesenteric vein thrombosis	1	0	1
Mouth haemorrhage	0	1	1
Mouth swelling	1	0	1
Nausea	268	165	433
Odynophagia	0	1	1
Oesophageal discomfort	0	1	1
Oral discomfort	1	1	2
Oral pain	0	1	1
Palatal disorder	1	0	1
Pancreatitis	1	0	1
Pancreatitis acute	1	0	1
Paraesthesia oral	0	1	1
Retching	2	2	4
Small intestinal haemorrhage	1	0	1
Stomatitis	0	1	1
Swollen tongue	1	0	1
Tongue coated	1	1	2
Toothache	0	1	1
Vomiting	34	24	58
General disorders and administration site conditions			
Administration site pain	1	0	1
Adverse event	0	1	1
Application site pain	0	1	1
Asthenia	33	29	62
Axillary pain	2	2	4

Brain death	1	0	1
Chest discomfort	17	12	29
Chest pain	21	18	39
Chills	397	231	628
Condition aggravated	4	1	5
Cyst	0	1	1
Death	12	0	12
Decreased activity	2	0	2
Discomfort	6	4	10
Disease recurrence	2	0	2
Drug ineffective	1	0	1
Exercise tolerance decreased	1	2	3
Extensive swelling of vaccinated limb	19	20	39
Face oedema	1	0	1
Facial discomfort	0	1	1
Facial pain	0	2	2
Fatigue	467	369	836
Feeling abnormal	3	11	14
Feeling cold	12	9	21
Feeling drunk	2	0	2
Feeling hot	7	10	17
Feeling of body temperature change	7	8	15
Feeling of relaxation	0	1	1
Gait disturbance	8	9	17
Gait inability	1	1	2
General physical health deterioration	4	0	4
Hyperpyrexia	0	1	1
Hypothermia	1	0	1
Ill-defined disorder	0	1	1
Illness	2	9	11
Inflammation	2	2	4
Influenza like illness	55	50	105
Injected limb mobility decreased	0	1	1
Injection site bruising	2	0	2
Injection site discolouration	0	1	1
Injection site discomfort	2	0	2
Injection site erythema	3	9	12
Injection site haematoma	1	0	1
Injection site hypoaesthesia	0	1	1
Injection site induration	0	4	4
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	26	40	66
Injection site paraesthesia	0	1	1
Injection site pruritus	0	3	3
Injection site rash	1	0	1
Injection site reaction	189	144	333
Injection site swelling	4	7	11

	Injection site warmth	0	4	4
	Malaise	328	215	543
	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	2	0	2
	Oedema peripheral	3	1	4
	Pain	19	27	46
	Peripheral swelling	8	11	19
	Pre-existing condition improved	1	0	1
	Pyrexia	424	318	742
	Sense of oppression	4	2	6
	Sluggishness	1	1	2
	Sudden death	2	0	2
	Swelling	4	0	4
	Swelling face	0	3	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	1	2
	Vaccination failure	7	0	7
	Vaccination site bruising	2	0	2
	Vaccination site pain	1	2	3
	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	8	13
	Immune system disorder	2	1	3
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	32	16	48
	COVID-19 pneumonia	2	0	2
	Conjunctivitis	1	0	1
	Cystitis	0	1	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 virus infection	0	1	1
	Herpes zoster	2	4	6
	Hordeolum	2	0	2
	Infection	1	0	1
	Influenza	1	1	2
	Injection site infection	1	0	1
	Meningitis viral	1	0	1
	Nasopharyngitis	5	17	22
	Oral herpes	0	2	2
	Oral infection	0	1	1
	Pharyngitis	1	1	2
	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
	Viral rash	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
	Heat stroke	0	1	1
	Inappropriate schedule of product administration	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 inappropriate	1	0	1
	Product administration error	0	1	1
Investigations	Blood HIV RNA increased	1	0	1
	Blood creatine phosphokinase increased	1	0	1
	Blood glucose increased	1	0	1
	Blood pressure decreased	3	0	3
	Blood pressure increased	2	5	7
	Body temperature increased	2	5	7
	C-reactive protein increased	5	2	7
	Electrocardiogram repolarisation abnormality	1	0	1
	Eosinophil count increased	0	1	1
	Fibrin D dimer increased	6	3	9
	Heart rate decreased	2	0	2
	Heart rate increased	12	14	26
	Heart rate irregular	0	1	1
	Heparin-induced thrombocytopenia test positive	1	0	1
	Hormone level abnormal	1	2	3
	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
	Platelet count increased	0	1	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	3	2	5
	White blood cell count decreased	0	1	1
Metabolism and nutrition disorders	Appetite disorder	1	0	1
	Decreased appetite	15	11	26
	Dehydration	3	1	4
	Fluid retention	0	1	1
Musculoskeletal and connective tissue disorders	Arthralgia	241	148	389
	Arthritis	2	0	2
	Arthropathy	1	0	1
	Axillary mass	0	1	1
	Back pain	21	23	44
	Bone pain	0	2	2
	Bursitis	2	0	2
	Epiphyseal disorder	1	0	1
	Flank pain	1	0	1
	Groin pain	2	0	2
	Joint ankylosis	1	0	1
	Joint stiffness	3	1	4
	Limb discomfort	15	17	32
	Muscle atrophy	1	0	1
	Muscle spasms	14	15	29
	Muscle tightness	1	1	2
	Muscular weakness	13	9	22
	Musculoskeletal chest pain	2	3	5
	Musculoskeletal discomfort	2	2	4
	Musculoskeletal pain	2	4	6
	Musculoskeletal stiffness	13	14	27
	Myalgia	403	310	713
	Neck pain	12	17	29
	Neuropathic muscular atrophy	1	0	1

	Nuchal rigidity	1	0	1
	Pain in extremity	47	57	104
	Pain in jaw	0	4	4
	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	6	9
	Allodynia	1	0	1
	Altered state of consciousness	2	0	2
	Amnesia	1	1	2
	Anosmia	4	3	7
	Balance disorder	6	7	13
	Bell's palsy	1	0	1
	Burning sensation	5	5	10
	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	1	2
	Coma	1	0	1
	Disturbance in attention	5	5	10
	Dizziness	42	39	81
	Dizziness postural	1	1	2
	Dysgeusia	2	10	12
	Dyskinesia	1	0	1
	Dysstasia	4	5	9
	Electric shock sensation	2	2	4
	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	6	4	10
	Headache	484	361	845
	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	7	17	24

Hypokinesia	1	0	1
Hypotonia	3	0	3
Intraventricular haemorrhage	1	0	1
Ischaemic stroke	2	0	2
Lethargy	0	1	1
Loss of consciousness	8	0	8
Memory impairment	2	1	3
Mental impairment	2	1	3
Meralgia paraesthetica	1	0	1
Migraine	12	12	24
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
Muscle spasticity	0	1	1
Narcolepsy	1	0	1
Nervous system disorder	6	6	12
Neuralgia	6	4	10
Neuralgic amyotrophy	2	0	2
Neurological symptom	1	0	1
Neuropathy peripheral	0	1	1
Ophthalmic migraine	1	0	1
Paraesthesia	25	34	59
Paralysis	1	0	1
Parosmia	0	5	5
Partial seizures	1	0	1
Presyncope	3	3	6
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	3	2	5
Sleep deficit	1	0	1
Somnolence	4	5	9
Speech disorder	2	2	4
Spinal cord disorder	1	0	1
Superior sagittal sinus thrombosis	1	0	1
Syncope	19	1	20
Taste disorder	2	1	3
Tremor	12	15	27
Trigeminal nerve disorder	0	1	1
Unresponsive to stimuli	1	0	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
Agitation	0	1	1
Algophobia	0	1	1
Anxiety	4	5	9
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	1	3
Dissociation	1	1	2
Emotional disorder	0	1	1
Emotional distress	0	1	1
Hallucination	4	0	4
Head banging	1	0	1
Hyposomnia	1	0	1
Initial insomnia	0	1	1
Insomnia	13	12	25
Irritability	0	1	1
Libido decreased	0	1	1
Listless	0	1	1
Loss of libido	0	1	1
Mental fatigue	0	1	1
Middle insomnia	3	0	3
Mood altered	0	2	2
Mood swings	1	0	1
Nightmare	1	1	2
Panic disorder	1	0	1
Paramnesia	0	1	1
Poor quality sleep	7	5	12
Restlessness	1	0	1
Sleep disorder	5	3	8
Terminal insomnia	1	0	1
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
Nocturia	0	1	1
Pollakiuria	1	0	1
Renal disorder	2	0	2
Renal infarct	1	0	1
Renal pain	3	3	6

	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	6	7
	Menstruation irregular	7	13	20
	Oligomenorrhoea	1	5	6
	Ovarian cyst	1	1	2
	Ovarian disorder	0	1	1
	Pelvic pain	2	0	2
	Polymenorrhoea	4	5	9
	Postmenopausal haemorrhage	4	0	4
	Premature menopause	0	1	1
	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
	Vulval disorder	0	1	1
	Vulvovaginal dryness	0	1	1
Vulvovaginal inflammation	1	0	1	
Respiratory, thoracic and mediastinal disorders	Aphonia	0	1	1
	Asphyxia	1	0	1
	Asthma	0	2	2
	Asthmatic crisis	1	0	1
	Choking sensation	1	0	1
	Cough	8	14	22
	Dysphonia	1	1	2
	Dyspnoea	29	35	64
	Dyspnoea at rest	1	0	1
	Dyspnoea exertional	1	0	1
	Epistaxis	2	6	8
	Haemoptysis	0	1	1
	Hyperventilation	3	3	6
	Increased upper airway secretion	0	1	1
	Lung disorder	2	0	2

Nasal congestion	2	1	3
Nasal obstruction	1	1	2
Oropharyngeal discomfort	1	0	1
Oropharyngeal pain	5	9	14
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
Pneumonitis	0	1	1
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	2	4
Respiratory arrest	1	0	1
Respiratory depth decreased	0	1	1
Respiratory disorder	5	7	12
Respiratory distress	2	0	2
Respiratory failure	4	0	4
Rhinorrhoea	5	5	10
Sinus pain	0	1	1
Sneezing	4	0	4
Throat irritation	0	2	2
Tracheal disorder	1	0	1
Vocal cord disorder	1	0	1
Vocal cord dysfunction	1	0	1
Wheezing	0	2	2
Yawning	1	0	1
Skin and subcutaneous tissue disorders			
Acne	2	0	2
Blood blister	1	0	1
Cold sweat	0	3	3
Dermatitis allergic	0	1	1
Dry skin	1	0	1
Ecchymosis	1	2	3
Eczema	1	1	2
Erythema	3	10	13
Erythema multiforme	1	0	1
Henoch-Schonlein purpura	1	0	1
Hyperhidrosis	30	19	49
Night sweats	2	2	4
Pain of skin	0	2	2
Papule	0	1	1
Petechiae	3	2	5
Piloerection	0	2	2
Pityriasis rosea	0	1	1
Pruritus	4	8	12
Psoriasis	3	1	4
Purpura	1	1	2

	Pyoderma gangrenosum	1	0	1
	Rash	10	5	15
	Rash erythematous	1	6	7
	Rash macular	6	4	10
	Rash papular	1	1	2
	Rash pruritic	3	3	6
	Sensitive skin	3	0	3
	Skin burning sensation	1	2	3
	Skin discolouration	0	1	1
	Skin disorder	58	48	106
	Skin irritation	1	0	1
	Skin mass	0	1	1
	Skin odour abnormal	2	0	2
	Skin reaction	0	1	1
	Skin warm	1	0	1
	Urticaria	6	6	12
Social circumstances	Bedridden	0	2	2
	Housebound	1	0	1
	Impaired driving ability	0	2	2
	Impaired work ability	5	5	10
	Loss of personal independence in daily activities	4	0	4
	Physical disability	1	0	1
	Pregnancy of partner	0	1	1
	Underimmunisation	0	1	1
Surgical and medical procedures	Bed rest	3	1	4
	COVID-19 immunisation	6	6	12
	Mechanical ventilation	1	0	1
	Pacemaker generated rhythm	1	0	1
	Thrombosis prophylaxis	0	1	1
Vascular disorders	Blood pressure fluctuation	0	1	1
	Cyanosis	2	0	2
	Deep vein thrombosis	5	0	5
	Haematoma	1	2	3
	Haemorrhage	1	0	1
	Hot flush	7	7	14
	Hypertension	7	5	12
	Hypertensive crisis	1	0	1
	Hypotension	8	5	13
	Hypovolaemic shock	1	0	1
	Microangiopathy	1	0	1
	Orthostatic hypotension	0	1	1
	Pallor	3	1	4
	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	1	2	3
	Vasculitis	2	0	2

Vasodilatation	1	2	3
Vein discolouration	1	0	1
Vein disorder	1	0	1
Venous occlusion	1	0	1
Total	4943	3833	8,776