

Summary Tabulation 22.03.2022

[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		4	1	5
Arrhythmia		5	0	5
Arteriospasm coronary		1	0	1
Cardiac arrest		2	0	2
Cardiac discomfort		1	0	1
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		10	3	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	4	0	4
	Palpitations	12	12	24
	Pericarditis	2	1	3
	Tachycardia	3	8	11
Ear and labyrinth disorders	Deafness	3	1	4
	Deafness unilateral	1	0	1
	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	21	13	34
	Vertigo	14	12	26
	Vestibular disorder	1	0	1
Endocrine disorders	Basedow's disease	0	1	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	1	1	2
	Blindness unilateral	2	0	2
	Cataract	1	0	1
	Chorioretinopathy	1	0	1
	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
	Swelling of eyelid	1	0	1
	Vision blurred	5	8	13
	Visual acuity reduced	3	0	3
	Visual impairment	4	4	8
Gastrointestinal disorders	Abdominal discomfort	3	1	4
	Abdominal distension	1	1	2
	Abdominal pain	20	3	23
	Abdominal pain lower	0	1	1
	Abdominal pain upper	6	6	12
	Aphthous ulcer	1	0	1
	Chapped lips	0	1	1
	Constipation	1	0	1
	Dental discomfort	1	0	1
	Diarrhoea	19	8	27
	Dry mouth	1	1	2
	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
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	210	62	272
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	27	16	43
General disorders and administration site conditions			
Administration site pain	1	0	1
Application site pain	0	1	1
Asthenia	28	16	44
Axillary pain	2	0	2
Chest discomfort	14	2	16
Chest pain	21	7	28
Chills	319	76	395
Condition aggravated	3	1	4
Death	11	0	11
Decreased activity	1	0	1
Discomfort	3	3	6
Disease recurrence	2	0	2
Drug ineffective	1	0	1
Exercise tolerance decreased	1	1	2
Extensive swelling of vaccinated limb	18	6	24
Face oedema	1	0	1
Facial pain	0	2	2
Fatigue	377	150	527
Feeling abnormal	2	7	9
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	7	5	12
Gait inability	0	2	2
General physical health deterioration	3	0	3

	Hypothermia	1	0	1
	Illness	2	8	10
	Inflammation	2	0	2
	Influenza like illness	44	23	67
	Injection site bruising	2	0	2
	Injection site discomfort	1	0	1
	Injection site erythema	3	2	5
	Injection site haematoma	1	0	1
	Injection site induration	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	19	26	45
	Injection site pruritus	0	1	1
	Injection site rash	1	0	1
	Injection site reaction	148	32	180
	Injection site swelling	3	1	4
	Injection site warmth	0	1	1
	Malaise	264	68	332
	Mucosal dryness	1	0	1
	Multiple organ dysfunction syndrome	1	0	1
	Oedema	1	0	1
	Oedema peripheral	2	0	2
	Pain	16	13	29
	Peripheral swelling	7	6	13
	Pre-existing condition improved	1	0	1
	Pyrexia	339	141	480
	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	6	0	6
	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	Allergy to arthropod bite	1	0	1
	Anaphylactic reaction	2	0	2
	Autoimmune disorder	4	0	4
	Hypersensitivity	5	5	10
	Immune system disorder	2	0	2
Infections and infestations	Appendicitis	1	0	1
	Asymptomatic COVID-19	1	0	1
	Bronchitis	2	0	2

	COVID-19	30	12	42
	COVID-19 pneumonia	2	0	2
	Conjunctivitis	1	0	1
	Ear infection	0	2	2
	Encephalitis	0	1	1
	Epididymitis	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	4	12	16
	Oral herpes	0	1	1
	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	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 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	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	2	4
	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	1	7
	Heart rate decreased	1	0	1
	Heart rate increased	11	5	16
	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
	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	6	20
	Dehydration	2	1	3
	Fluid retention	0	1	1
Musculoskeletal and connective tissue disorders	Arthralgia	196	51	247
	Arthritis	2	0	2
	Arthropathy	1	0	1
	Back pain	14	12	26
	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	0	3
	Limb discomfort	9	6	15
	Muscle atrophy	1	0	1
	Muscle spasms	12	6	18
	Muscle tightness	1	1	2
	Muscular weakness	11	8	19
	Musculoskeletal chest pain	2	0	2
	Musculoskeletal discomfort	2	0	2
	Musculoskeletal pain	2	0	2
	Musculoskeletal stiffness	10	9	19
	Myalgia	319	107	426
	Neck pain	8	6	14
	Neuropathic muscular atrophy	1	0	1
	Nuchal rigidity	1	0	1

	Pain in extremity	30	26	56
	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
	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	1	4
	Allodynia	1	0	1
	Altered state of consciousness	2	0	2
	Amnesia	1	0	1
	Anosmia	3	1	4
	Balance disorder	5	3	8
	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	1	5	6
	Dizziness	36	25	61
	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	2	0	2
	Facial paresis	1	0	1
	Febrile convulsion	1	0	1
	Guillain-Barre syndrome	4	0	4
	Head discomfort	4	2	6
	Headache	381	144	525
	Hemianopia	1	0	1
	Hemiparesis	1	0	1
	Hemiplegia	2	0	2
	Horner's syndrome	1	0	1
	Hyperaesthesia	0	1	1
	Hyperreflexia	0	1	1
	Hypersomnia	2	4	6
	Hypoaesthesia	6	3	9
	Hypokinesia	1	0	1
	Hypotonia	2	0	2

	Ischaemic stroke	2	0	2
	Loss of consciousness	8	0	8
	Memory impairment	1	0	1
	Mental impairment	1	0	1
	Meralgia paraesthetica	1	0	1
	Migraine	10	2	12
	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	22	14	36
	Paralysis	1	0	1
	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	2	2
	Sciatica	0	1	1
	Seizure	2	0	2
	Sensory disturbance	0	3	3
	Sensory loss	2	3	5
	Somnolence	2	4	6
	Speech disorder	2	2	4
	Spinal cord disorder	1	0	1
	Superior sagittal sinus thrombosis	1	0	1
	Syncope	12	1	13
	Taste disorder	1	1	2
	Tremor	11	11	22
	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	1	1	2
	Apathy	0	1	1
	Confusional state	4	1	5
	Conversion disorder	1	0	1
	Delirium	2	0	2
	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
	Hyposomnia	1	0	1
	Insomnia	11	5	16
	Irritability	0	1	1
	Libido decreased	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	0	5
	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
	Nephrolithiasis	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	4	19	23
	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	11	20
	Hypomenorrhoea	1	1	2
	Intermenstrual bleeding	2	6	8
	Menometrorrhagia	1	3	4
	Menstrual disorder	7	12	19
	Menstruation delayed	1	5	6
	Menstruation irregular	7	13	20
	Oligomenorrhoea	1	5	6
	Ovarian cyst	1	1	2
	Pelvic pain	1	0	1

	Polymenorrhoea	4	5	9
	Postmenopausal haemorrhage	4	0	4
	Premenstrual pain	0	1	1
	Testicular pain	1	2	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
	Asthmatic crisis	1	0	1
	Cough	8	8	16
	Dysphonia	1	0	1
	Dyspnoea	21	19	40
	Dyspnoea at rest	1	0	1
	Dyspnoea exertional	1	0	1
	Epistaxis	2	6	8
	Haemoptysis	0	1	1
	Hyperventilation	3	0	3
	Lung disorder	2	0	2
	Nasal congestion	2	0	2
	Nasal obstruction	0	1	1
	Oropharyngeal discomfort	1	0	1
	Oropharyngeal pain	5	4	9
	Paranasal sinus discomfort	0	1	1
	Pharyngeal oedema	1	0	1
	Pharyngeal swelling	2	0	2
	Pleural effusion	2	0	2
	Pleurisy	1	0	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	1	1	2
	Respiratory arrest	1	0	1
	Respiratory disorder	4	4	8
	Respiratory distress	2	1	3
	Respiratory failure	4	0	4
	Rhinorrhoea	5	0	5
	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
	Yawning	1	0	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	3	5	8
	Erythema multiforme	1	0	1
	Henoch-Schonlein purpura	1	0	1
	Hyperhidrosis	25	11	36
	Night sweats	1	1	2
	Pain of skin	0	1	1
	Petechiae	3	2	5
	Piloerection	0	1	1
	Pruritus	4	3	7
	Psoriasis	3	0	3
	Purpura	1	1	2
	Pyoderma gangrenosum	1	0	1
	Rash	8	1	9
	Rash erythematous	1	1	2
	Rash macular	5	1	6
	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	48	16	64
	Skin odour abnormal	2	0	2
	Skin reaction	0	1	1
	Urticaria	6	0	6
Social circumstances	Bedridden	0	1	1
	Housebound	1	0	1
	Impaired driving ability	0	2	2
	Impaired work ability	3	5	8
	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	6	2	8
	Pacemaker generated rhythm	1	0	1
Vascular disorders	Cyanosis	2	0	2
	Deep vein thrombosis	5	0	5
	Haematoma	1	1	2
	Haemorrhage	1	0	1
	Hot flush	7	1	8
	Hypertension	6	3	9
	Hypertensive crisis	1	0	1
	Hypotension	5	2	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	2	2
Vasculitis	1	0	1
Vasodilatation	0	1	1
Vein discolouration	1	0	1
Vein disorder	1	0	1
Venous occlusion	1	0	1
Total	3993	1672	5,665