

**Summary Tabulation 2021.08.24**

| Active Substance (High Level)        | COVID-19 VACCINE JANSSEN (AD26.COV2.S) | Serious | Non Serious | Total |
|--------------------------------------|--|---------|-------------|-------|
| Reaction SOC                         | Reaction PT                            |         |             |       |
| Blood and lymphatic system disorders | Coagulopathy                           | 8       | 0           | 8     |
|                                      | Disseminated intravascular coagulation | 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    |
|                                      | Myocardial fibrosis                    | 1       | 0           | 1     |
|                                      | Myocardial infarction                  | 1       | 0           | 1     |
|                                      | Myocardial ischaemia                   | 1       | 0           | 1     |
|                                      | Myocardial oedema                      | 1       | 0           | 1     |
|                                      | Myocarditis                            | 4       | 0           | 4     |
|                                      | Palpitations                           | 7       | 5           | 12    |
|                                      | Pericarditis                           | 1       | 1           | 2     |
|                                      | Tachycardia                            | 2       | 3           | 5     |
| Ear and labyrinth disorders          | Deafness                               | 3       | 1           | 4     |
|                                      | Ear discomfort                         | 0       | 1           | 1     |
|                                      | Ear pain                               | 1       | 1           | 2     |
|                                      | Hyperacusis                            | 1       | 0           | 1     |
|                                      | Hypoacusis                             | 1       | 0           | 1     |
|                                      | Motion sickness                        | 1       | 0           | 1     |
|                                      | Tinnitus                               | 9       | 4           | 13    |
|                                      | Vertigo                                | 7       | 7           | 14    |
| 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                                | 1   | 0  | 1   |
| Ocular hyperaemia                                    | 0   | 1  | 1   |
| Photophobia  | 2   | 0  | 2   |
| Retinal detachment                                   | 1   | 0  | 1   |
| Vision blurred                                       | 3   | 3  | 6   |
| Visual acuity reduced                                | 2   | 0  | 2   |
| Visual impairment                                    | 3   | 2  | 5   |
| Gastrointestinal disorders                           |     |    |     |
| Abdominal discomfort                                 | 2   | 0  | 2   |
| Abdominal pain                                       | 14  | 1  | 15  |
| Abdominal pain lower                                 | 0   | 1  | 1   |
| Abdominal pain upper                                 | 4   | 3  | 7   |
| Aphthous ulcer                                       | 1   | 0  | 1   |
| Chapped lips   | 0   | 1  | 1   |
| Constipation   | 1   | 0  | 1   |
| Dental discomfort                                    | 1   | 0  | 1   |
| Diarrhoea  | 12  | 3  | 15  |
| Dry mouth  | 0   | 1  | 1   |
| Dyspepsia  | 1   | 0  | 1   |
| Dysphagia  | 1   | 0  | 1   |
| Faeces discoloured                                   | 1   | 0  | 1   |
| Flatulence   | 1   | 0  | 1   |
| Frequent bowel movements                             | 1   | 0  | 1   |
| Haematemesis   | 1   | 0  | 1   |
| Hypoesthesia 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   | 155 | 37 | 192 |
| 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   | 19  | 7  | 26  |
| General disorders and administration site conditions |     |    |     |
| Application site pain                                | 0   | 1  | 1   |
| Asthenia   | 17  | 8  | 25  |
| Chest discomfort                                     | 9   | 2  | 11  |
| Chest pain   | 10  | 3  | 13  |
| Chills   | 234 | 36 | 270 |
| Condition aggravated                                 | 1   | 0  | 1   |
| Death  | 9   | 0  | 9   |

|                         |                                       |     |    |     |
|-------------------------|---------------------------------------|-----|----|-----|
|                         | Discomfort                            | 3   | 3  | 6   |
|                         | Disease recurrence                    | 1   | 0  | 1   |
|                         | Extensive swelling of vaccinated limb | 12  | 0  | 12  |
|                         | Face oedema                           | 1   | 0  | 1   |
|                         | Fatigue                               | 265 | 70 | 335 |
|                         | Feeling abnormal                      | 1   | 2  | 3   |
|                         | Feeling cold                          | 6   | 2  | 8   |
|                         | Feeling hot                           | 4   | 6  | 10  |
|                         | Feeling of body temperature change    | 3   | 3  | 6   |
|                         | Feeling of relaxation                 | 0   | 1  | 1   |
|                         | Gait disturbance                      | 5   | 3  | 8   |
|                         | General physical health deterioration | 2   | 0  | 2   |
|                         | Illness                               | 2   | 7  | 9   |
|                         | Inflammation                          | 1   | 0  | 1   |
|                         | Influenza like illness                | 29  | 14 | 43  |
|                         | 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                   | 8   | 17 | 25  |
|                         | Injection site pruritus               | 0   | 1  | 1   |
|                         | Injection site rash                   | 1   | 0  | 1   |
|                         | Injection site reaction               | 96  | 9  | 105 |
|                         | Injection site swelling               | 2   | 1  | 3   |
|                         | Malaise                               | 196 | 32 | 228 |
|                         | Multiple organ dysfunction syndrome   | 1   | 0  | 1   |
|                         | Oedema                                | 1   | 0  | 1   |
|                         | Oedema peripheral                     | 1   | 0  | 1   |
|                         | Pain                                  | 9   | 8  | 17  |
|                         | Peripheral swelling                   | 2   | 3  | 5   |
|                         | Pre-existing condition improved       | 1   | 0  | 1   |
|                         | Pyrexia                               | 258 | 83 | 341 |
|                         | Sense of oppression                   | 4   | 0  | 4   |
|                         | Sluggishness                          | 1   | 1  | 2   |
|                         | Sudden death                          | 2   | 0  | 2   |
|                         | Swelling                              | 2   | 0  | 2   |
|                         | Temperature regulation disorder       | 1   | 0  | 1   |
|                         | Therapeutic response unexpected       | 0   | 1  | 1   |
|                         | Therapy non-responder                 | 5   | 0  | 5   |
|                         | Thirst                                | 0   | 1  | 1   |
|                         | Thirst decreased                      | 1   | 0  | 1   |
|                         | Vaccination failure                   | 1   | 0  | 1   |
|                         | Vaccination site bruising             | 2   | 0  | 2   |
| 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   | 2  | 5   |

|   |  |     |    |     |
|---|--|-----|----|-----|
|   | Immune system disorder                         | 1   | 0  | 1   |
| Infections and infestations                     | Appendicitis                                   | 1   | 0  | 1   |
|   | COVID-19                                       | 2   | 2  | 4   |
|   | Genital herpes                                 | 1   | 0  | 1   |
|   | 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   |
|   | Nasopharyngitis                                | 0   | 7  | 7   |
|   | Oral infection                                 | 0   | 1  | 1   |
|   | Pneumonia                                      | 1   | 0  | 1   |
|   | Septic shock                                   | 1   | 0  | 1   |
|   | Suspected COVID-19                             | 1   | 0  | 1   |
| Injury, poisoning and procedural complications  | Contusion                                      | 0   | 3  | 3   |
|   | Fall   | 4   | 0  | 4   |
|   | Muscle injury                                  | 0   | 1  | 1   |
|   | Nasal injury                                   | 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                     | 0   | 2  | 2   |
|   | C-reactive protein increased                   | 2   | 1  | 3   |
|   | Fibrin D dimer increased                       | 4   | 0  | 4   |
|   | Heart rate increased                           | 9   | 2  | 11  |
|   | Heparin-induced thrombocytopenia test positive | 1   | 0  | 1   |
|   | International normalised ratio 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   |
|   | 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                             | 12  | 3  | 15  |
|   | Dehydration                                    | 1   | 0  | 1   |
|   | Fluid retention                                | 0   | 1  | 1   |
| Musculoskeletal and connective tissue disorders | Arthralgia                                     | 128 | 19 | 147 |
|   | Back pain                                      | 12  | 5  | 17  |
|   | Bone pain                                      | 0   | 1  | 1   |
|   | Bursitis                                       | 2   | 0  | 2   |
|   | Groin pain                                     | 1   | 0  | 1   |
|   | Limb discomfort                                | 7   | 3  | 10  |
|   | Muscle spasms                                  | 5   | 3  | 8   |

|   |                                |     |     |     |
|---|--------------------------------|-----|-----|-----|
| Muscle tightness  | 1                              | 0   | 1   |     |
| Muscular weakness   | 4                              | 5   | 9   |     |
| Musculoskeletal discomfort  | 1                              | 0   | 1   |     |
| Musculoskeletal stiffness   | 7                              | 8   | 15  |     |
| Myalgia   | 226                            | 51  | 277 |     |
| Neck pain   | 3                              | 4   | 7   |     |
| Nuchal rigidity   | 1                              | 0   | 1   |     |
| Pain in extremity   | 12                             | 14  | 26  |     |
| 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                      | 28  | 17  | 45  |
|   | Dizziness postural             | 1   | 0   | 1   |
|   | Dysgeusia                      | 1   | 6   | 7   |
|   | Dyskinesia                     | 1   | 0   | 1   |
|   | Dysstasia                      | 2   | 1   | 3   |
|   | Electric shock sensation       | 2   | 1   | 3   |
|   | Facial paresis                 | 1   | 0   | 1   |
|   | Febrile convulsion             | 1   | 0   | 1   |
|   | Head discomfort                | 3   | 1   | 4   |
|   | Headache                       | 273 | 78  | 351 |
|   | Hemiparesis                    | 1   | 0   | 1   |
|   | Hemiplegia                     | 1   | 0   | 1   |
|   | Hyperreflexia                  | 0   | 1   | 1   |
|   | Hypersomnia                    | 0   | 1   | 1   |
|   | Hypoesthesia                   | 3   | 0   | 3   |
|   | Hypokinesia                    | 1   | 0   | 1   |
|   | Hypotonia                      | 1   | 0   | 1   |
|   | Loss of consciousness          | 4   | 0   | 4   |
|   | 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                             | 9 | 5 | 14 |
|  | 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                             | 0 | 2 | 2  |
|  | 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                                 | 8 | 3 | 11 |
|  | Irritability                             | 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                           | 1 | 0 | 1  |
|  | Renal infarct                            | 1 | 0 | 1  |
|  | Renal pain                               | 2 | 1 | 3  |
|  | 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 | 0 | 1  |
|  | Menstrual disorder                       | 1 | 0 | 1  |

|   |                            |    |   |    |
|---|----------------------------|----|---|----|
|   | Menstruation delayed       | 1  | 1 | 2  |
|   | 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  | 4 | 8  |
|   | Dyspnoea                   | 11 | 9 | 20 |
|   | 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         | 3  | 0 | 3  |
|   | Pulmonary infarction       | 1  | 0 | 1  |
|   | Pulmonary oedema           | 1  | 0 | 1  |
|   | Respiratory disorder       | 1  | 2 | 3  |
|   | Respiratory distress       | 1  | 1 | 2  |
|   | Respiratory failure        | 3  | 0 | 3  |
|   | Rhinorrhoea                | 2  | 0 | 2  |
|   | Sneezing                   | 1  | 0 | 1  |
| Skin and subcutaneous tissue disorders          | Throat irritation          | 0  | 1 | 1  |
|   | Acne                       | 1  | 0 | 1  |
|   | Blood blister              | 1  | 0 | 1  |
|   | Dry skin                   | 1  | 0 | 1  |
|   | Ecchymosis                 | 0  | 1 | 1  |
|   | Erythema                   | 0  | 3 | 3  |
|   | Henoch-Schonlein purpura   | 1  | 0 | 1  |
|   | Hyperhidrosis              | 20 | 2 | 22 |
|   | 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              | 30 | 3 | 33 |
|   | 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           | 1          | 1            |
|                                 | Impaired work ability                             | 0           | 5          | 5            |
|                                 | Loss of personal independence in daily activities | 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                                      | 2           | 2          | 4            |
|                                 | Hypotension                                       | 3           | 2          | 5            |
|                                 | Hypovolaemic shock                                | 1           | 0          | 1            |
|                                 | Microangiopathy                                   | 1           | 0          | 1            |
|                                 | Pallor  | 2           | 1          | 3            |
|                                 | Peripheral coldness                               | 3           | 0          | 3            |
|                                 | Phlebitis   | 1           | 0          | 1            |
|                                 | 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>2619</b> | <b>773</b> | <b>3.392</b> |

Rows 1 - 364 (All Rows)