

EU Local Number	EV Primary Report Date	Report Type	Primary Disease Qualification	Primary Source Country Registry Reference	Literature Reference	Patient Age Group	Patient Age (years at report)	Patient Sex	Patient Status	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intending Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
EU-EC-1001025347	07/10/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Blood test (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disability), Coronary artery disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disability), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disability), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disability), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disability), Muscle pain (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Hemoptysis (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition)	ZYPREXA 5 MG COATED TABLETS (OLANZAPINE) (S - Depression - Not applicable - [n/a - 5mg - Once Daily]) VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE (S - Depression - Not applicable - [n/a - 75mg - Once Daily]) COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Product used for unknown indication - Not applicable - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1001024418	06/10/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001024027	06/10/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Not Specified	No	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001022970	05/10/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001022917	05/10/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001022919	05/10/2021	Sporadic	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Bacterial infection (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Diabetic ketoacidosis (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal infection (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) ESOMEPRAZOLE (ESOMEPRAZOLE) (C - Abdominal pain upper - n/a - [n/a - n/a - Unknown]) LANTUS (INSULIN GLARGINE) (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]) SUNARBY 1 MG/100 MG (METFORMIN HYDROCHLORIDE, PARALGOLIC ACID) (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]) [GEMEPHRIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]) [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - Unknown]) [METFORMIN, METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]) [NATTOXINASE] (C - Thrombosis - n/a - [n/a - n/a - Unknown]) [NIBVOLOL, NIBVOLOL HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - n/a - Unknown]) [PANTOPRAZOL, PANTOPRAZOL, PANTOPRAZOL SODIUM] (C - Hypertension - n/a - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001020871	04/10/2021	Sporadic	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001021455	04/10/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death), Fall (n/a - Unknown - Results in Death), Vibration (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001021405	30/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Fatigue (100 - Unknown -), Hypothyroidism (100 - Unknown -), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Unknown -), Polymers chain reaction positive (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (100 - Unknown -)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (SUSPENSION FOR INJECTION (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-1001019887	29/09/2021	Sporadic	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Tremor (n/a - Unknown - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001017073	29/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Aerococcosis (n/a - Fatal - Results in Death), Alopecia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Mononuclear infection (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]) [FENOFENADINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [FLUTICASON PROPRIONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001017039	29/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Acute hepatic failure (n/a - Fatal - Results in Death), Acute left ventricular failure (n/a - Fatal - Results in Death), Angiogram cerebral abnormal (n/a - Fatal - Results in Death), Brain death (n/a - Fatal - Results in Death), Brain herniation (n/a - Fatal - Results in Death), Brain oedema (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Computed tomogram head abnormal (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Diabetic shock (n/a - Fatal - Results in Death), Electrocardiogram abnormal (n/a - Fatal - Results in Death), Endotracheal intubation (n/a - Fatal - Results in Death), Gastrointestinal haemorrhage (n/a - Fatal - Results in Death), Hemiparesis (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Intensive care (n/a - Fatal - Results in Death), Intracranial pressure increased (n/a - Fatal - Results in Death), Laboratory test (n/a - Fatal - Results in Death), Lactic acidosis (n/a - Fatal - Results in Death), Mental status changes (n/a - Fatal - Results in Death), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pupil fixed (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001017039	29/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Angiogram abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral palsy syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebellar ataxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral mass effect (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coma scale abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computed tomogram head abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Computed tomogram neck (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dysphagia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Electroencephalogram (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic-induced thrombocytopenia test (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hydrocephalus (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nix stroke scale abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Paranasal sinus deconcent (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Perfusion brain scan (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Platelet count normal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Posterior fossa syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Status like phenomena (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Status epilepticus (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thalamic infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tinnitus (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001015119	29/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Embolism arterial (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001015116	29/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001015197	29/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Anticoagulant therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest X-ray abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computed tomogram (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computed tomogram thorax (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Computed tomogram thorax abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depression (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive airway pressure therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive expiratory pressure therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [DILOROLAMINE, DILOROLAMINE SULPHATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [DIPYRIDOL, DIPYRIDOL HYDROCHLORIDE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [TRIAMCLOLOLONE ACETONIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001015197	29/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Anticoagulant therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depression (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oxygen saturation abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive airway pressure therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Positive expiratory pressure therapy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Productive cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachypnea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) [DEXAMETHASONE DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [PROLIA (DENOSUMAB)] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [ASCOBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [ASCOBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [BROCALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [SORAZIPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [ESOMEPRAZOLE, ESOMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [ESOMEPRAZOLE, ESOMEPRAZOLE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [PRAZOSIN, PRAZOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]) [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001014579	27/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	Cerebral failure (n/a - Unknown - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001014580	27/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 pneumonia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Gait stability (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Glucose urine present (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001012389	24/09/2021	Sporadic	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001009829	22/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bacterial test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Completed tomogram head abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Completed tomogram thorax normal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mycobacteria mycosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Post procedural haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rash (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Subpharyngeal infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Subpharyngeal infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Subpharyngeal infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Subpharyngeal infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tracheostomy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Transfusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) [LINDAMYCIN, CLINDAMYCIN PHOSPHATE] (C - Product used for unknown indication - n/a - [n/a - 400mg - Oral]) [ACYCLOVIR] (C - Product used for unknown indication - n/a - [n/a - 250mg - Unknown]) [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral])	Not reported	CSR
EU-EC-1001008275	21/09/2021	Sporadic	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (RECOMBINANT) JANSSEN (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1001008827	21/09/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Elderly	Female	No	Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Angiogram abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) (COVID-19 VACCINE JANSSEN (AD26.COV2.S) (S - Immunisation - Not applicable - [n/a - n/a - Unknown]) [APRIBAN (PARIBAN) (C - n/a - n/a - [n/a - 250mg - Unknown]) [AMOXICILIN, AMOXICILIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 250mg - Unknown])	Not reported	CSR

EU Local Number	EV Primary Report Date	Report Type	Primary Reporter Country Regulatory Authority	Literature Reference	Patient Age Group (at per report)	Patient Sex	Patient Onset Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intending Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form	
								Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hematuria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)				
EU-EC-1000463647	28/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000464233	28/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Elderly	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000464303	28/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000464602	28/04/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000464833	28/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
								Back pain (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Epistaxis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Hemoptysis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Increased viscosity of upper respiratory secretion (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Secretion discharge (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition), Thrombosis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition)				
EU-EC-1000464867	27/04/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	[LOGARTAN, LOGARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000464156	26/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Not Specified	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000464190	26/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000464301	23/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000387135	21/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000354058	19/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000354029	18/04/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Not Specified	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000191517	05/04/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000191963	05/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	More than 18 Years	Elderly	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
								Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial embolism (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)				
EU-EC-1000164406	01/04/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000152972	31/03/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000135560	30/03/2021	Sporadic	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000138806	30/03/2021	Sporadic	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	COVID-19 VACCINE JANSSEN (AZD1222.2) (COVID-19 VACCINE JANSSEN (AZD1222.2)) (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR
								Abdominal pain upper (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Erythema (n/a - Unknown - Results in Death), Fatigue (n/a - Unknown - Results in Death), Headache (n/a - Unknown - Results in Death), Pain in extremity (n/a - Unknown - Results in Death), Pallor (n/a - Unknown - Results in Death), Pre-existing condition aggravated (n/a - Unknown - Results in Death)				