

AstraZeneca COVID-19 batch AB0002 Vaccine Analysis Print

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports received associated with AstraZeneca COVID-19 vaccine batch AB0002 up to and including 15/09/2026

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Case Count	Fatal Count
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	Anaemia	1	0
	Haematological disorders NEC	Haematological disorders	Bone marrow oedema	1	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	2	0
			Thrombocytopenia	2	0
			Thrombosis with thrombocytopenia syndrome	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	4	0
			Lymphadenitis	1	0
			Lymphadenopathy	50	0
			Splenic infarction	1	0
	White blood cell disorders	Leukopenias NEC	Leukopenia	1	0
		Neutropenias	Neutropenia	4	0
Cardiac disorders	Cardiac arrhythmias	Cardiac conduction disorders	Atrioventricular block	1	0
		Rate and rhythm disorders NEC	Bradycardia	2	0
			Cardiac flutter	1	0
			Extrasystoles	1	0
			Postural orthostatic tachycardia syndrome	2	0
			Tachyarrhythmia	1	0
			Tachycardia	43	0
		Supraventricular arrhythmias	Atrial fibrillation	1	0
			Atrial flutter	1	0
			Sinus tachycardia	4	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	1	1
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiac disorder	1	0
		Cardiac signs and symptoms NEC	Palpitations	65	0
	Cardiac valve disorders	Mitral valvular disorders	Mitral valve disease	1	0
		Tricuspid valvular disorders	Tricuspid valve disease	1	0
	Coronary artery disorders	Coronary artery disorders NEC	Coronary artery occlusion	1	0
		Ischaemic coronary artery disorders	Angina pectoris	5	0
			Myocardial infarction	6	2
			Myocardial ischaemia	2	2
	Heart failures	Heart failures NEC	Cardiac failure	2	0
	Myocardial disorders	Noninfectious myocarditis	Myocarditis	1	0
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	3	0
		Pericardial disorders NEC	Pericardial effusion	1	0
Congenital, familial and genetic disorders	Musculoskeletal and connective tissue disorders congenital	Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	Branchial cyst	1	0
	Neurological disorders congenital	Central nervous system disorders congenital NEC	Neural tube defect	1	1
			Spina bifida	1	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear discomfort	1	0
			Ear pain	25	0
			External ear pain	1	0
			Auditory disorder	1	0
	External ear disorders (excl congenital)	Hearing disorders NEC	Deafness	4	0
			Hypoacusis	2	0
			Hyperacusis	3	0
			Motion sickness	2	0
	Hearing disorders	Hearing losses	Tinnitus	18	0
			Vertigo	23	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms			
Endocrine disorders	Adrenal gland disorders	Adrenal cortical hyperfunctions	Cushingoid	1	0
	Endocrine disorders of gonadal function	Female gonadal function disorders	Polycystic ovarian syndrome	1	0

Eye disorders	Hypothalamus and pituitary gland disorders	Hypothalamic and pituitary disorders NEC	Hypothalamo-pituitary disorder	1	0
	Eye disorders NEC	Lacrimation disorders	Dry eye	8	0
			Lacrimation increased	1	0
		Ocular disorders NEC	Eye oedema	1	0
			Eye pain	41	0
			Eye swelling	10	0
			Ocular discomfort	1	0
			Periorbital swelling	2	0
	Ocular haemorrhages and vascular disorders NEC	Conjunctival and corneal bleeding and vascular disorders	Conjunctival haemorrhage	1	0
		Ocular bleeding and vascular disorders NEC	Eye haemorrhage	1	0
	Ocular infections, irritations and inflammations	Iris and uveal tract infections, irritations and inflammations	Uveitis	2	0
			Eye allergy	1	0
		Ocular infections, inflammations and associated manifestations	Eye irritation	4	0
			Eye pruritus	5	0
			Ocular hyperaemia	6	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Blepharospasm	1	0
			Eyelid ptosis	2	0
		Ocular nerve and muscle disorders	Eye movement disorder	1	0
		Pupil disorders	Anisocoria	1	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	1	0
			Foreign body sensation in eyes	2	0
			Photophobia	15	0
	Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit and degeneration	Vitreous floaters	1	0
		Retinal structural change, deposit and degeneration	Macular degeneration	1	0
	Retina, choroid and vitreous haemorrhages and vascular disorders	Retinal bleeding and vascular disorders (excl retinopathy)	Retinal haemorrhage	1	0
		Retinopathies NEC	Retinal exudates	1	0
	Vision disorders	Visual disorders NEC	Diplopia	4	0
			Photopsia	6	0
			Vision blurred	17	0
		Visual field disorders	Visual field defect	1	0
		Visual impairment and blindness (excl colour blindness)	Blindness	2	0
			Visual acuity reduced	2	0
			Visual impairment	4	0
Gastrointestinal disorders	Anal and rectal conditions NEC	Anal and rectal signs and symptoms	Anal hypoaesthesia	1	0
	Dental and gingival conditions	Dental pain and sensation disorders	Hyperaesthesia teeth	1	0
			Toothache	3	0
		Gingival disorders, signs and symptoms NEC	Gingival pain	2	0
			Gingival swelling	1	0
		Gingival haemorrhages	Gingival bleeding	1	0
	Exocrine pancreas conditions	Acute and chronic pancreatitis	Pancreatitis	1	0
	Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Gastric haemorrhage	1	0
		Intestinal haemorrhages	Rectal haemorrhage	1	0
		Non-site specific gastrointestinal haemorrhages	Haematemesis	1	0
			Haematochezia	2	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis	1	0
			Colitis ulcerative	2	0
		Gastritis (excl infective)	Gastritis	1	0
			Reflux gastritis	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	119	0
		Gastrointestinal atonic and hypomotility disorders NEC	Gastrooesophageal reflux disease	1	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	10	0
			Eructation	3	0
		Flatulence, bloating and distension	Abdominal distension	4	0
			Flatulence	6	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	62	0
			Abdominal pain lower	3	0

General disorders and administration site conditions		Gastrointestinal signs and symptoms NEC	Abdominal pain upper	65	0
			Abdominal rigidity	1	0
			Gastrointestinal pain	2	0
			Abdominal discomfort	14	0
			Dysphagia	4	0
		Nausea and vomiting symptoms	Nausea	599	0
			Retching	6	0
			Vomiting	195	0
			Vomiting projectile	1	0
	Gastrointestinal ulceration and perforation	Gastric ulcers and perforation	Gastric ulcer	1	0
		Peptic ulcers and perforation	Peptic ulcer haemorrhage	1	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Lip blister	1	0
			Lip disorder	1	0
			Oral lichen planus	1	0
			Oral blood blister	1	0
		Oral soft tissue haemorrhages	Hypoaesthesia oral	8	0
			Oral pain	2	0
			Oral pruritus	1	0
			Paraesthesia oral	12	0
		Oral soft tissue swelling and oedema	Lip swelling	14	0
			Mouth swelling	3	0
		Stomatitis and ulceration	Aphthous ulcer	1	0
			Mouth ulceration	6	0
			Stomatitis	1	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	18	0
			Lip dry	1	0
			Salivary hypersecretion	1	0
			Parotid gland enlargement	1	0
	Tongue conditions	Tongue signs and symptoms	Swollen tongue	5	0
			Tongue discomfort	1	0
	Administration site reactions	Administration site reactions NEC	Administration site bruise	1	0
			Administration site erythema	1	0
			Administration site pain	1	0
			Puncture site bruise	1	0
			Puncture site pain	2	0
			Puncture site reaction	1	0
			Vessel puncture site bruise	1	0
		Application site reactions	Application site bruise	1	0
		Infusion site reactions	Infusion site warmth	1	0
		Injection site reactions	Injected limb mobility decreased	1	0
			Injection site bruising	2	0
			Injection site discomfort	1	0
			Injection site erythema	8	0
			Injection site inflammation	2	0
			Injection site mass	21	0
			Injection site oedema	1	0
			Injection site pain	84	0
			Injection site pruritus	7	0
			Injection site rash	3	0
			Injection site reaction	1	0
			Injection site swelling	8	0
			Injection site vesicles	1	0
			Injection site warmth	6	0
		Vaccination site reactions	Vaccination site bruising	2	0
			Vaccination site discolouration	1	0
			Vaccination site discomfort	1	0

		Vaccination site erythema	9	0
		Vaccination site inflammation	2	0
		Vaccination site mass	8	0
		Vaccination site movement impairment	2	0
		Vaccination site pain	34	0
		Vaccination site pruritus	3	0
		Vaccination site rash	3	0
		Vaccination site swelling	9	0
		Vaccination site warmth	4	0
Body temperature conditions	Febrile disorders	Hyperpyrexia	4	0
		Masked fever	1	0
		Pyrexia	1,072	0
Complications associated with device	Complications associated with device NEC	Medical device site joint pain	1	0
Fatal outcomes	Death and sudden death	Brain death	1	0
		Death	12	12
		Sudden death	1	1
General system disorders NEC	Asthenic conditions	Asthenia	77	0
		Chronic fatigue syndrome	2	0
		Fatigue	771	0
		Malaise	211	0
	Feelings and sensations NEC	Chills	720	0
		Feeling abnormal	20	0
		Feeling cold	85	0
		Feeling drunk	1	0
		Feeling hot	17	0
		Feeling of body temperature change	16	0
		Hangover	2	0
		Hunger	1	0
		Sensation of foreign body	1	0
		Temperature intolerance	2	0
		Thirst	20	0
	Gait disturbances	Gait disturbance	6	0
		Gait inability	4	0
		Loss of control of legs	1	0
	General signs and symptoms NEC	Condition aggravated	8	0
		Crying	4	0
		Energy increased	1	0
		Exercise tolerance decreased	1	0
		Glassy eyes	1	0
		Illness	66	0
		Influenza like illness	151	0
		Local reaction	6	0
		Peripheral swelling	92	0
		Secretion discharge	2	0
		Swelling	29	0
		Swelling face	9	0
	Inflammations	Inflammation	12	0
	Mucosal findings abnormal	Mucosal dryness	1	0
	Oedema NEC	Face oedema	2	0
		Localised oedema	1	0
		Oedema	1	0
		Oedema peripheral	2	0
	Pain and discomfort NEC	Axillary pain	7	0
		Chest discomfort	36	0
		Chest pain	70	0
		Discomfort	4	0

			Facial pain	2	0
			Inflammatory pain	1	0
			Pain	323	0
			Tenderness	18	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	1	0
		Therapeutic and nontherapeutic responses	Adverse drug reaction	1	0
			Drug ineffective	7	0
			Remission not achieved	1	0
			Therapeutic response unexpected	1	0
			Vaccination failure	1	0
	Tissue disorders NEC	Fibrosis NEC	Fibrosis	1	0
		Mass conditions NEC	Cyst	1	0
			Mass	2	0
		Ulcers NEC	Ulcer	1	0
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Hepatocellular damage and hepatitis NEC	Liver injury	1	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergic oedema	1	0
			Hypersensitivity	13	0
			Type III immune complex mediated reaction	1	0
		Allergies to foods, food additives, drugs and other chemicals	Drug hypersensitivity	1	0
			Food allergy	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	7	0
		Autoimmune disorders NEC	Autoimmune disorder	1	0
	Immune disorders NEC	Immune and associated conditions NEC	Bacille Calmette-Guerin scar reactivation	1	0
Infections and infestations	Ancillary infectious topics	Infectious transmissions	Secondary transmission	1	0
	Bacterial infectious disorders	Bacterial infections NEC	Cellulitis	14	0
			Vaccination site cellulitis	2	0
	Fungal infectious disorders	Candida infections	Candida infection	1	0
		Fungal infections NEC	Fungal infection	2	0
	Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Diverticulitis	1	0
			Ear infection	2	0
		Ear infections	Labyrinthitis	1	0
			Infection	3	0
			Injection site infection	1	0
			Vaccination site infection	1	0
		Lower respiratory tract and lung infections	Lower respiratory tract infection	4	0
			Pneumonia	7	2
			Pneumonia aspiration	3	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	1	0
			Septic rash	1	0
		Skin structures and soft tissue infections	Skin infection	1	0
		Upper respiratory tract infections	Nasopharyngitis	21	0
			Pharyngitis	2	0
			Rhinitis	3	0
			Sinusitis	2	0
			Tonsillitis	1	0
		Urinary tract infections	Kidney infection	1	0
			Urinary tract infection	4	0
	Rickettsial infectious disorders	Coxiella infections	Q fever	3	0
Viral infectious disorders	Viral infectious disorders	Coronavirus infections	COVID-19	56	7
			COVID-19 pneumonia	5	3
			Post-acute COVID-19 syndrome	1	0
			Suspected COVID-19	1	0
		Epstein-Barr viral infections	Infectious mononucleosis	1	0
		Herpes viral infections	Herpes simplex	1	0
			Herpes zoster	12	0
			Oral herpes	9	0

Injury, poisoning and procedural complications		Influenza viral infections	Influenza	92	0		
		Viral infections NEC	Gastroenteritis viral	2	0		
			Pneumonia viral	1	0		
			Sweating fever	15	0		
			Vestibular neuronitis	1	0		
			Viral infection	1	0		
	Exposures, chemical injuries and poisoning	Chemical injuries	Chemical phlebitis	1	0		
			Exposure during pregnancy	1	0		
			Exposure via breast milk	1	0		
			Foetal exposure during pregnancy	2	0		
			Maternal exposure during breast feeding	7	0		
			Maternal exposure during pregnancy	4	0		
			Exposures to agents or circumstances NEC	Exposure to SARS-CoV-2	1	0	
			Exposures associated with pregnancy, delivery and lactation	Barotrauma	1	0	
		Chillblains		2	0		
		Heat exhaustion		1	0		
		Sunburn		1	0		
		Thermal burn		1	0		
		Thermal burns of eye		1	0		
		Injuries by physical agents	Ear injuries NEC	Ear canal injury	1	0	
			Eye injuries NEC	Eye injury	1	0	
			Muscle, tendon and ligament injuries	Muscle injury	2	0	
			Nerve injuries NEC	Nerve injury	3	0	
			Non-site specific injuries NEC	Extraskeletal ossification	1	0	
	Fall			3	0		
	Injuries NEC	Renal and urinary tract injuries NEC	Kidney rupture	2	0		
			Site specific injuries NEC	Limb injury	1	0	
			Skin injuries NEC	Contusion	26	0	
			Accidental exposures to product	Accidental exposure to product	1	0	
			Medication errors, product use errors and issues NEC	Medication error	2	0	
			Product administration errors and issues	Extra dose administered	1	0	
		Medication errors and other product use errors and issues	Inappropriate schedule of product administration	1	0		
			Off label uses and intentional product misuses/use issues	Off label use	2	0	
			Overdoses and underdoses NEC	Intentional underdose	1	0	
			Procedural related injuries and complications NEC	Injection related reaction	5	0	
				Immunisation reaction	1	0	
			Investigations	Cardiac and vascular investigations (excl enzyme tests)	Heart rate and pulse investigations	Heart rate	10
					Heart rate decreased	1	0
		Heart rate increased			19	0	
		Heart rate irregular			4	0	
		Maximum heart rate decreased			1	0	
		Pulse abnormal			1	0	
Vascular tests NEC (incl blood pressure)		Blood pressure abnormal			1	0	
	Blood pressure decreased	4			0		
	Blood pressure diastolic	1			0		
	Blood pressure increased	8			0		
	Endocrine investigations (incl sex hormones)	Hormone level abnormal			1	0	
	Haematology investigations (incl blood groups)	Blood counts NEC			Full blood count abnormal	1	0
Coagulation and bleeding analyses		International normalised ratio decreased			1	0	
		International normalised ratio increased			1	0	
		Platelet count decreased		3	0		
Platelet analyses		Platelet count decreased		3	0		
Immunology and allergy investigations		Immunoglobulin analyses		Blood immunoglobulin E increased	1	0	
Lipid analyses	Cholesterol analyses	Blood cholesterol increased		1	0		
Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased		5	0		
	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose fluctuation		1	0		

	Microbiology and serology investigations	Virus identification and serology	Blood glucose increased	1	0
			SARS-CoV-2 test	2	0
			SARS-CoV-2 test positive	34	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body surface area	1	0
			Body temperature	20	0
			Body temperature abnormal	4	0
			Body temperature decreased	4	0
			Body temperature fluctuation	3	0
			Body temperature increased	22	0
			Respiratory rate decreased	1	0
			Skin temperature	8	0
			Weight decreased	6	0
	Renal and urinary tract investigations and urinalyses	Urinary tract function analyses NEC	Urine output	1	0
	Respiratory and pulmonary investigations (excl blood gases)	Respiratory and pulmonary function diagnostic procedures	Peak expiratory flow rate	1	0
	Toxicology and therapeutic drug monitoring	Therapeutic drug monitoring analyses	Anticoagulation drug level above therapeutic	1	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood iron decreased	1	0
			Blood potassium decreased	1	0
			Blood potassium increased	1	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	125	0
			Hypophagia	2	0
			Increased appetite	1	0
		General nutritional disorders NEC	Abnormal loss of weight	1	0
			Feeding disorder	3	0
			Food aversion	1	0
	Electrolyte and fluid balance conditions	Fluid intake increased	Polydipsia	1	0
		Potassium imbalance	Hyperkalaemia	1	0
		Sodium imbalance	Hyponatraemia	2	0
		Total fluid volume decreased	Dehydration	8	0
		Total fluid volume increased	Fluid retention	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Type 2 diabetes mellitus	1	0
		Hyperglycaemic conditions NEC	Hyperglycaemia	1	0
		Hypoglycaemic conditions NEC	Hypoglycaemia	2	0
	Purine and pyrimidine metabolism disorders	Disorders of purine metabolism	Gout	1	0
	Vitamin related disorders	Fat soluble vitamin deficiencies and disorders	Vitamin D deficiency	1	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone disorders NEC	Bone disorder	1	0
			Bone pain	19	0
		Bone related signs and symptoms	Pain in jaw	8	0
			Spinal pain	3	0
			Polymyalgia rheumatica	2	0
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Arthritis	5	0
			Arthropathy	3	0
			Rheumatic fever	1	0
		Joint related disorders NEC	Joint lock	1	0
			Periarthritis	3	0
			Arthralgia	377	0
		Joint related signs and symptoms	Joint stiffness	6	0
			Joint swelling	16	0
			Joint warmth	1	0
		Osteoarthropathies	Osteoarthritis	2	0
		Psoriatic arthropathies	Psoriatic arthropathy	1	0
		Rheumatoid arthropathies	Rheumatoid arthritis	4	0
			Still's disease	1	0
			Arthritis reactive	1	0
	Muscle disorders	Spondyloarthropathies	Fibromyalgia	2	0
		Muscle pains	Myalgia	463	0
			Muscle fatigue	14	0
		Muscle related signs and symptoms NEC			

			Muscle spasms	43	0	
			Muscle tightness	3	0	
			Muscle twitching	6	0	
		Muscle tone abnormalities	Trismus	2	0	
		Muscle weakness conditions	Muscular weakness	28	0	
		Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)	Extremity deformities	Finger deformity	2	0
		Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Mobility decreased	11	0
				Musculoskeletal stiffness	46	0
				Back pain	95	0
				Flank pain	2	0
	Limb discomfort			29	0	
	Musculoskeletal and connective tissue pain and discomfort		Musculoskeletal chest pain	6	0	
			Musculoskeletal discomfort	1	0	
			Musculoskeletal pain	4	0	
			Neck pain	32	0	
			Pain in extremity	264	0	
	Soft tissue disorders NEC	Axillary mass	1	0		
		Neck mass	1	0		
		Soft tissue mass	1	0		
		Bursitis	2	0		
		Tendonitis	1	0		
Synovial and bursal disorders	Bursal disorders	Trigger finger	1	0		
Tendon, ligament and cartilage disorders	Tendon disorders	Breast cancer	1	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasms malignant and unspecified (incl nipple)	Oesophageal squamous cell carcinoma	1	0		
	Gastrointestinal neoplasms malignant and unspecified	Haemangioma	1	0		
	Miscellaneous and site unspecified neoplasms benign	Noninfective encephalitis	1	0		
Nervous system disorders	Central nervous system infections and inflammations	Encephalitis NEC	Brain stem infarction	1	0	
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral haemorrhage	3	1	
			Cerebral infarction	3	0	
			Cerebrovascular accident	20	2	
			Embolic stroke	1	1	
			Haemorrhage intracranial	1	1	
			Ischaemic stroke	1	0	
			Lacunar stroke	1	0	
			Middle cerebral artery stroke	1	0	
			Subarachnoid haemorrhage	1	0	
			Cerebral venous thrombosis	1	1	
			Superior sagittal sinus thrombosis	1	0	
			Transient ischaemic attack	8	0	
			VIth nerve paralysis	1	0	
			Bell's palsy	5	0	
			Facial paralysis	4	0	
	Facial paresis	1	0			
	Facial spasm	1	0			
	Olfactory nerve disorders	Anosmia	7	0		
		Hyposmia	1	0		
		Parosmia	11	0		
		Phantosmia	1	0		
		Optic neuritis	1	0		
	Headaches	Headaches NEC	Cluster headache	10	0	
			Cold-stimulus headache	1	0	
			Drug withdrawal headache	1	0	
			Exertional headache	1	0	
			Headache	1,217	0	
			Primary stabbing headache	1	0	
			Sinus headache	15	0	

	Migraine headaches	Tension headache	12	0
		Thunderclap headache	1	0
		Hemiplegic migraine	2	0
		Migraine	84	0
		Migraine with aura	3	0
		Migraine without aura	2	0
		Ophthalmic migraine	1	0
		Vestibular migraine	1	0
Increased intracranial pressure and hydrocephalus	Increased intracranial pressure disorders	Intracranial pressure increased	2	0
Mental impairment disorders	Memory loss (excl dementia)	Amnesia	2	0
		Memory impairment	3	0
	Mental impairment (excl dementia and memory loss)	Cognitive disorder	1	0
		Disturbance in attention	8	0
		Mental impairment	4	0
Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Akathisia	2	0
		Bradykinesia	1	0
		Clumsiness	1	0
		Hypokinesia	1	0
		Movement disorder	2	0
	Paralysis and paresis (excl cranial nerve)	Diplegia	2	0
		Hemiparesis	3	0
		Hemiplegia	4	0
		Monoplegia	3	0
		Paralysis	5	0
		Paraplegia	1	0
	Parkinson's disease and parkinsonism	Freezing phenomenon	1	0
	Tremor (excl congenital)	Asterixis	1	0
		Tremor	147	0
Neurological disorders NEC	Abnormal reflexes	Areflexia	1	0
	Coma states	Coma	1	0
	Coordination and balance disturbances	Balance disorder	15	0
		Coordination abnormal	4	0
		Dysstasia	5	0
	Cortical dysfunction NEC	Aphasia	3	0
	Disturbances in consciousness NEC	Altered state of consciousness	1	0
		Depressed level of consciousness	2	0
		Lethargy	84	0
		Loss of consciousness	12	0
		Somnolence	34	0
		Syncope	40	0
	Neurological signs and symptoms NEC	Brain fog	10	0
		Dizziness	269	0
		Dizziness exertional	1	0
		Dizziness postural	29	0
		Head discomfort	3	0
		Myoclonus	1	0
		Neurological symptom	1	0
		Presyncope	8	0
		Unresponsive to stimuli	2	0
	Paraesthesias and dysaesthesias	Burning sensation	9	0
		Formication	1	0
		Hyperaesthesia	1	0
		Hypoaesthesia	57	0
		Paraesthesia	91	0
		Vibration syndrome	2	0
	Sensory abnormalities NEC	Ageusia	11	0

			Allodynia	1	0	
			Dysgeusia	29	0	
			Electric shock sensation	1	0	
			Hypogeusia	1	0	
			Neuralgia	12	0	
			Restless legs syndrome	3	0	
			Sensory loss	2	0	
			Taste disorder	9	0	
			Speech and language abnormalities	Dysarthria	8	0
				Incoherent	1	0
	Slow speech	1		0		
	Speech disorder	2		0		
	Neuromuscular disorders	Autonomic nervous system disorders	Autonomic nervous system imbalance	2	0	
		Neuromuscular disorders NEC	Muscle contractions involuntary	1	0	
	Peripheral neuropathies	Acute polyneuropathies Peripheral neuropathies NEC	Muscle spasticity	1	0	
			Guillain-Barre syndrome	3	0	
			Neuropathy peripheral	2	0	
			Peripheral motor neuropathy	1	0	
			Peripheral sensory neuropathy	1	0	
			Polyneuropathy	1	0	
Seizures (incl subtypes)	Seizures and seizure disorders NEC	Epilepsy	3	0		
		Febrile convulsion	1	0		
		Partial seizures	1	0		
		Seizure	13	0		
		Tonic convulsion	1	0		
Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	4	0		
	Sleep disturbances NEC	Sleep deficit	2	0		
Spinal cord and nerve root disorders	Lumbar spinal cord and nerve root disorders	Sciatica	2	0		
Structural brain disorders	Structural brain disorders NEC	Brain injury	1	0		
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions spontaneous	1	0		
Product issues	Device issues	Device malfunction events NEC	Thrombosis in device	2	0	
	Product quality, supply, distribution, manufacturing and quality system issues	Product physical issues	Product taste abnormal	1	0	
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	5	0	
			Anxiety	12	0	
			Nervousness	9	0	
			Stress	3	0	
			Tension	1	0	
			Fear symptoms and phobic disorders (incl social phobia)	Agoraphobia	1	0
		Phonophobia		1	0	
		Obsessive-compulsive disorders and symptoms	Obsessive-compulsive disorder	1	0	
			Panic attacks and disorders	Panic attack	3	0
		Panic reaction		2	0	
		Changes in physical activity	Increased physical activity levels	Restlessness	7	0
			Cognitive and attention disorders and disturbances	Mental fatigue	8	0
	Communication disorders and disturbances	Speech and language usage disturbances	Disorganised speech	1	0	
		Deliria (incl confusion)	Confusion and disorientation	Confusional state	35	0
	Disorientation			8	0	
	Deliria		Delirium	5	0	
			Depressed mood disorders and disturbances	Depressive disorders	Depression	4
	Mood alterations with depressive symptoms	Decreased interest			1	0
		Depressed mood		9	0	
		Tearfulness		2	0	
	Dissociative disorders	Dissociative states	Dissociation	1	0	
	Disturbances in thinking and perception	Delusional symptoms	Delusion	2	0	
		Hallucinations (excl sleep-related)	Hallucination	16	0	
			Hallucination, visual	1	0	

Renal and urinary disorders	Mood disorders and disturbances NEC	Perception disturbances NEC	Autoscopy	1	0
			Derealisation	1	0
			Perceptual disturbance	1	0
			Time perception altered	1	0
		Thinking disturbances	Bradyphrenia	2	0
			Tachyphrenia	1	0
			Thinking abnormal	2	0
		Affect alterations NEC	Flat affect	1	0
		Emotional and mood disturbances NEC	Anger	1	0
			Emotional disorder	2	0
	Personality disorders and disturbances in behaviour		Emotional distress	1	0
			Frustration tolerance decreased	1	0
			Irritability	4	0
			Mood altered	1	0
		Fluctuating mood symptoms	Mood swings	1	0
		Mood disorders NEC	Listless	2	0
		Behaviour and socialisation disturbances	Indifference	1	0
		Disturbances in initiating and maintaining sleep	Insomnia	50	0
			Middle insomnia	1	0
		Dyssomnias	Poor quality sleep	2	0
	Sleep disorders and disturbances	Parasomnias	Abnormal dreams	7	0
			Nightmare	9	0
			Sleep terror	1	0
			Sleep disorder	9	0
		Sleep disorders NEC	Habit cough	1	0
		Somatic symptom disorders	Suicidal ideation	4	0
		Suicidal and self-injurious behaviours NEC	Urinary tract disorder	1	0
		Genitourinary tract disorders NEC	Acute kidney injury	1	0
		Renal disorders (excl nephropathies)	Oliguria	1	0
			Renal impairment	1	0
Reproductive system and breast disorders	Urinary tract signs and symptoms	Bladder and urethral symptoms	Dysuria	2	0
			Incontinence	3	0
			Micturition urgency	1	0
			Pollakiuria	9	0
			Urinary incontinence	1	0
		Urinary abnormalities	Chromaturia	2	0
			Haematuria	3	0
		Urinary tract signs and symptoms NEC	Polyuria	1	0
			Renal pain	10	0
	Breast disorders	Breast signs and symptoms	Breast pain	7	0
			Breast tenderness	1	0
		Lactation disorders	Lactation disorder	1	0
		Menopause related conditions	Menopausal symptoms	1	0
			Premature menopause	1	0
			Postmenopausal haemorrhage	2	0
		Menopausal effects on the genitourinary tract	Dysmenorrhoea	6	0
		Menstruation and uterine bleeding NEC	Intermenstrual bleeding	3	0
			Menstrual disorder	8	0
			Menstruation irregular	14	0
	Menstrual cycle and uterine bleeding disorders		Premenstrual pain	2	0
		Menstruation with decreased bleeding	Amenorrhoea	4	0
			Hypomenorrhoea	1	0
			Menstruation delayed	18	0
			Oligomenorrhoea	1	0
		Menstruation with increased bleeding	Heavy menstrual bleeding	14	0
			Polymenorrhoea	3	0

Respiratory, thoracic and mediastinal disorders	Ovarian and fallopian tube disorders	Ovarian and fallopian tube disorders NEC	Premature ovulation	1	0
	Reproductive tract disorders NEC	Reproductive tract disorders NEC (excl neoplasms)	Genital ulceration	2	0
		Reproductive tract signs and symptoms NEC	Pelvic pain	4	0
	Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular oedema	1	0
			Testicular pain	2	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal cysts and neoplasms	Bartholin's cyst	1	0
			Vaginal cyst	1	0
		Vulvovaginal disorders NEC	Vaginal haemorrhage	17	0
	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	6	0
			Wheezing	7	0
	Lower respiratory tract disorders (excl obstruction and infection)	Parenchymal lung disorders NEC	Pulmonary fibrosis	1	0
	Pleural disorders	Pleural infections and inflammations	Pleurisy	2	0
		Pneumothorax and pleural effusions NEC	Pleural effusion	1	1
	Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	17	3
			Pulmonary thrombosis	1	1
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	101	0
			Dyspnoea exertional	2	0
			Hyperventilation	2	0
			Hypopnoea	4	0
			Respiration abnormal	1	0
			Respiratory distress	1	0
			Sleep apnoea syndrome	2	0
			Tachypnoea	1	0
		Conditions associated with abnormal gas exchange	Hypoxia	2	0
		Coughing and associated symptoms	Cough	90	0
			Haemoptysis	2	0
			Productive cough	2	0
			Sputum discoloured	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Pulmonary pain	3	0
		Respiratory signs and symptoms NEC	Respiratory symptom	2	0
		Upper respiratory tract signs and symptoms	Aphonia	1	0
			Dry throat	6	0
			Dysphonia	2	0
			Oropharyngeal pain	61	0
			Paranasal sinus discomfort	1	0
			Rhinorrhoea	17	0
			Sinus pain	7	0
			Sneezing	4	0
			Throat irritation	2	0
			Throat tightness	2	0
	Upper respiratory tract disorders (excl infections)	Nasal congestion and inflammations	Nasal congestion	5	0
		Nasal disorders NEC	Epistaxis	11	0
			Nasal dryness	1	0
		Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	2	0
		Pharyngeal disorders (excl infections and neoplasms)	Oropharyngeal swelling	1	0
			Pharyngeal paraesthesia	1	0
			Pharyngeal swelling	3	0
			Tonsillar hypertrophy	1	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	8	0
		Urticarias	Urticaria	30	0
	Epidermal and dermal conditions	Bullous conditions	Blister	7	0
			Blood blister	1	0
			Pemphigoid	2	0
		Dermal and epidermal conditions NEC	Dermatosis	1	0
			Dry skin	6	0
			Pain of skin	26	0

			Sensitive skin	11	0	
			Skin burning sensation	11	0	
			Skin discolouration	3	0	
			Skin disorder	1	0	
			Skin reaction	6	0	
			Skin sensitisation	2	0	
			Skin swelling	1	0	
			Skin warm	5	0	
		Dermatitis and eczema	Dermatitis	3	0	
			Dermatitis allergic	2	0	
			Dermatitis contact	1	0	
			Eczema	3	0	
			Seborrhoeic dermatitis	1	0	
			Skin irritation	5	0	
		Dermatitis ascribed to specific agent	Drug reaction with eosinophilia and systemic symptoms	1	0	
		Erythemas	Erythema	50	0	
		Exfoliative conditions	Skin exfoliation	3	0	
		Papulosquamous conditions	Lichen planus	1	0	
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	3	0	
		Pruritus NEC	Pruritus	91	0	
		Psoriatic conditions	Psoriasis	6	0	
		Rashes, eruptions and exanthems NEC	Rash	95	0	
			Rash erythematous	28	0	
			Rash macular	5	0	
			Rash morbilliform	1	0	
			Rash papular	6	0	
			Rash pruritic	26	0	
			Rash vesicular	1	0	
	Skin injuries and mechanical dermatoses	Needle track marks	1	0		
		Panniculitides	Erythema nodosum	1	0	
		Skin and subcutaneous tissue ulcerations	Skin erosion	1	0	
	Skin appendage conditions	Acnes	Acne	1	0	
			Alopecias	Alopecia	2	0
		Apocrine and eccrine gland disorders	Cold sweat	33	0	
			Hyperhidrosis	144	0	
			Hypohidrosis	1	0	
			Miliaria	4	0	
			Night sweats	32	0	
		Pilar disorders NEC	Piloerection	2	0	
		Rosaceas	Rosacea	1	0	
	Skin vascular abnormalities	Purpura and related conditions	Petechiae	2	0	
		Skin vasomotor conditions	Livedo reticularis	1	0	
	Social circumstances	Lifestyle issues	Disability issues	Bedridden	1	0
				Immobile	1	0
Surgical and medical procedures	Cardiac therapeutic procedures	Cardiac therapeutic procedures NEC	Pericardial excision	1	0	
	Soft tissue therapeutic procedures	Muscle therapeutic procedures	Muscle relaxant therapy	1	0	
	Therapeutic procedures and supportive care NEC	Immunisations	COVID-19 immunisation	1	0	
			Immunisation	2	0	
		Therapeutic procedures NEC	Hospitalisation	1	0	
		Rest regimen	1	0		
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Non-site specific necrosis and vascular insufficiency NEC	Arterial occlusive disease	1	0	
		Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral artery occlusion	1	0	
			Peripheral coldness	20	0	
			Peripheral ischaemia	1	1	
			Raynaud's phenomenon	3	0	
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	3	0	

		Shock	2	0
	Vascular hypotensive disorders	Hypotension	13	0
Embolism and thrombosis	Non-site specific embolism and thrombosis	Embolism	2	0
		Thrombosis	12	1
	Peripheral embolism and thrombosis	Deep vein thrombosis	11	0
		Thrombophlebitis	1	0
Lymphatic vessel disorders	Lymphoedemas	Lymphoedema	1	0
Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	4	0
		Flushing	7	0
		Hot flush	40	0
	Site specific vascular disorders NEC	Pallor	9	0
Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	4	0
		Haemorrhage	8	0
		Internal haemorrhage	1	0
		Hypertensive crisis	1	0
Vascular hypertensive disorders	Accelerated and malignant hypertension	Hypertension	22	0
Vascular infections and inflammations	Vascular hypertensive disorders NEC	Phlebitis	1	0
	Phlebitis NEC	Vasculitis	3	0
	Vasculitides NEC	Varicose vein	1	0
Venous varices	Varicose veins NEC			
Total number of reports			3,190	
Total number of reactions			12,100	
Total number of fatal reports			44	
Total number of fatal reactions			44	