

Hepatitis A Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Hepatitis A vaccine up to and including 5th May 2025.

Report run: 06/05/2025

Earliest reaction date: 01/04/1992

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	Anaemia	2	0
		Marrow depression and hypoplastic anaemias	Aplastic anaemia	1	1
			Pancytopenia	1	0
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Haemorrhagic disorder	1	0
		Coagulopathies	Disseminated intravascular coagulation	2	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	5	0
			Thrombocytopenia	2	0
			Thrombocytopenic purpura	1	0
			Thrombotic thrombocytopenic purpura	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenitis	2	0
			Lymphadenopathy	25	0
		Spleen disorders	Splenomegaly	1	0
	White blood cell disorders	Leukocytoses NEC	Leukocytosis	1	0
			Lymphocytosis	1	0
		Neutropenias	Neutropenia	3	0
	Total			49	1
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	5	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG T Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Extrasystoles	1	0
			Tachycardia	11	0
		Supraventricular arrhythmias	Atrial fibrillation	2	0
		Ventricular arrhythmias and cardiac arrest	Cardio-respiratory arrest neonatal	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiac disorder	1	0
		Cardiac signs and symptoms NEC	Palpitations	7	0
	Heart failures	Heart failures NEC	Ventricular failure	1	0
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	2	0
	Total			31	0
Congenital, familial and genetic disorders	Cardiac and vascular disorders congenital	Cardiac septal defects congenital	Atrial septal defect	1	0
	Congenital and hereditary disorders NEC	Congenital disorders NEC	Congenital anomaly	3	0
	Eye disorders congenital	Lens disorders congenital	Lens abnormality, congenital	1	0
	Musculoskeletal and connective tissue disorders congenital	Musculoskeletal and connective tissue disorders of limbs congenital	Congenital musculoskeletal disorder of limbs	1	0
			Syndactyly	1	0
			Talipes	2	0
	Renal and urinary tract disorders congenital	Renal and urinary tract disorders congenital NEC	Congenital hydronephrosis	1	0
			Urinary tract malformation	1	0
		Renal disorders congenital	Kidney malformation	2	0
	Total			13	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear discomfort	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Hearing disorders	Hearing losses	Ear pain	5	0
			Deafness	2	0
			Deafness neurosensory	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Inner ear disorder	1	0
			Tinnitus	4	0
		Inner ear signs and symptoms	Vertigo	15	0
	Middle ear disorders (excl congenital)	Tympanic membrane disorders (excl infections)	Tympanic membrane disorder	1	0
	Total			30	0
Endocrine disorders	Thyroid gland disorders	Thyroid hyperfunction disorders	Hyperthyroidism	1	0
		Thyroid hypofunction disorders	Hypothyroidism	1	0
	Total			2	0
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye disorder	2	0
			Eye pain	2	0
			Eye swelling	5	0
			Periorbital oedema	3	0
	Ocular infections, irritations and inflammations	Conjunctival infections, irritations and inflammations	Conjunctivitis allergic	1	0
		Iris and uveal tract infections, irritations and inflammations	Iritis	1	0
			Uveitis	1	0
		Lid, lash and lacrimal infections, irritations and inflammations	Eyelid oedema	1	0
			Swelling of eyelid	2	0
		Ocular infections, inflammations and associated manifestations	Eye irritation	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Eye pruritus	2	0
			Ocular hyperaemia	2	0
	Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	14	0
			Oculogyric crisis	1	0
		Pupil disorders	Mydriasis	6	0
			Pupil fixed	1	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Photophobia	3	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	Retinal pigmentation	1	0
	Vision disorders	Visual colour distortions	Chromatopsia	1	0
		Visual disorders NEC	Diplopia	3	0
			Vision blurred	16	0
		Visual field disorders	Visual field defect	2	0
		Visual impairment and blindness (excl colour blindness)	Blindness	3	0
			Visual acuity reduced	1	0
			Visual impairment	7	0
	Total			84	0
Gastrointestinal disorders	Dental and gingival conditions	Dental pain and sensation disorders	Toothache	1	0
	Exocrine pancreas conditions	Acute and chronic pancreatitis	Pancreatitis	2	0
			Pancreatitis haemorrhagic	1	0
		Pancreatic disorders NEC	Pancreatic disorder	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	3	0
	Gastrointestinal haemorrhages NEC	Intestinal haemorrhages	Rectal haemorrhage	1	0
		Non-site specific gastrointestinal haemorrhages	Haematemesis	2	0
			Haematochezia	1	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis ulcerative	1	0
		Gastrointestinal inflammatory disorders NEC	Enteritis	1	0
		Oesophagitis (excl infective)	Oesophagitis	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	57	0
			Diarrhoea haemorrhagic	1	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	1	0
			Gastric dilatation	2	0
			Gastrooesophageal reflux disease	3	0
		Gastrointestinal spastic and hypermotility disorders	Irritable bowel syndrome	1	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	3	0
			Eructation	1	0
		Faecal abnormalities NEC	Abnormal faeces	1	0
			Faeces discoloured	1	0
			Faeces pale	3	0
		Flatulence, bloating and distension	Abdominal distension	5	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	44	0
			Abdominal pain lower	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Abdominal pain upper	30	0
			Abdominal rigidity	1	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	9	0
			Dysphagia	4	0
		Nausea and vomiting symptoms	Nausea	175	0
			Retching	3	0
			Vomiting	94	0
			Vomiting projectile	3	0
	Gastrointestinal ulceration and perforation	Gastric ulcers and perforation	Gastric ulcer haemorrhage	1	0
	Malabsorption conditions	Malabsorption syndromes	Steatorrhoea	1	0
	Oral soft tissue conditions	Oral soft tissue signs and symptoms	Hypoaesthesia oral	2	0
			Oral discomfort	1	0
			Oral pain	2	0
			Paraesthesia oral	1	0
		Oral soft tissue swelling and oedema	Lip oedema	1	0
			Lip swelling	16	0
			Mouth swelling	1	0
		Stomatitis and ulceration	Lip ulceration	1	0
			Mouth ulceration	7	0
	Peritoneal and retroperitoneal conditions	Peritoneal and retroperitoneal fibrosis and adhesions	Retroperitoneal fibrosis	1	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Salivary gland enlargements	Parotid gland enlargement	1	0
	Tongue conditions	Tongue disorders	Tongue ulceration	1	0
		Tongue signs and symptoms	Glossodynia	2	0
			Swollen tongue	5	0
			Tongue coated	1	0
			Tongue movement disturbance	1	0
		Total			510
	General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site swelling	1
Injection site reactions			Injection site atrophy	1	0
			Injection site bruising	1	0
			Injection site erythema	1	0
			Injection site hypoaesthesia	1	0
			Injection site inflammation	8	0
			Injection site irritation	1	0
			Injection site mass	1	0
			Injection site necrosis	1	0
			Injection site pain	33	0
			Injection site pruritus	1	0
			Injection site rash	1	0
			Injection site reaction	36	0
			Injection site swelling	3	0
			Injection site vesicles	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Injection site warmth	1	0
		Vaccination site reactions	Vaccination site erythema	2	0
			Vaccination site induration	1	0
			Vaccination site pain	3	0
			Vaccination site reaction	1	0
			Vaccination site swelling	1	0
	Body temperature conditions	Body temperature altered	Hypothermia	1	0
		Febrile disorders	Pyrexia	175	0
	Fatal outcomes	Death and sudden death	Death	1	1
			Sudden death	1	1
	General system disorders NEC	Asthenic conditions	Asthenia	29	0
			Chronic fatigue syndrome	9	0
			Fatigue	90	0
			Malaise	151	0
		Feelings and sensations NEC	Chills	46	0
			Feeling abnormal	10	0
			Feeling cold	5	0
			Feeling hot	15	0
			Feeling of body temperature change	4	0
			Hangover	1	0
			Thirst	5	0
		Gait disturbances	Gait disturbance	7	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Gait inability	1	0
		General signs and symptoms NEC	Condition aggravated	4	0
			Crying	1	0
			Disease recurrence	1	0
			Glassy eyes	1	0
			Illness	9	0
			Influenza like illness	87	0
			Local reaction	24	0
			Peripheral swelling	17	0
			Swelling	12	0
			Swelling face	21	0
		Inflammatons	Inflammation	3	0
		Oedema NEC	Face oedema	4	0
			Generalised oedema	2	0
			Oedema	3	0
			Oedema peripheral	5	0
		Pain and discomfort NEC	Chest discomfort	11	0
			Chest pain	8	0
			Discomfort	1	0
			Facial pain	2	0
			Pain	32	0
			Tenderness	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	1	0
			Potentiating drug interaction	1	0
		Therapeutic and nontherapeutic responses	Drug ineffective	2	0
			Vaccination failure	10	0
	Tissue disorders NEC	Mass conditions NEC	Cyst	1	0
	Total			916	2
Hepatobiliary disorders	Bile duct disorders	Bile duct infections and inflammations	Biliary colic	1	0
	Gallbladder disorders	Cholecystitis and cholelithiasis	Cholelithiasis	2	0
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Cholestasis	1	0
			Hepatitis cholestatic	1	0
			Jaundice	59	1
			Jaundice cholestatic	2	0
		Hepatic enzymes and function abnormalities	Hepatic function abnormal	5	0
			Hypertransaminasaemia	1	0
		Hepatic failure and associated disorders	Hepatic failure	1	0
			Hepatorenal failure	1	0
		Hepatobiliary signs and symptoms	Hepatomegaly	4	0
			Liver tenderness	3	0
		Hepatocellular damage and hepatitis NEC	Autoimmune hepatitis	5	0
			Granulomatous liver disease	1	0
			Hepatitis	16	0
			Hepatitis acute	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Liver injury	2	0
	Total			106	1
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergic oedema	1	0
			Allergy to metals	1	0
			Hypersensitivity	17	0
			Serum sickness	1	0
		Allergies to foods, food additives, drugs and other chemicals	Milk allergy	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	39	0
			Anaphylactic shock	8	0
			Anaphylactoid reaction	7	0
	Immune disorders NEC	Acute and chronic sarcoidosis	Sarcoidosis	1	0
		Immune and associated conditions NEC	Haemophagocytic lymphohistiocytosis	1	0
			Immune system disorder	1	0
	Total			78	0
Infections and infestations	Bacterial infectious disorders	Aeromonas infections	Aeromonas infection	1	0
		Bacterial infections NEC	Cellulitis	6	0
			Vaccination site cellulitis	2	0
		Salmonella infections	Typhoid fever	2	0
		Staphylococcal infections	Furuncle	1	0
	Fungal infectious disorders	Candida infections	Oral candidiasis	1	0
	Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Gastroenteritis	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Central nervous system and spinal infections	Brain abscess	1	0
			Encephalitis	4	0
			Meningitis aseptic	1	0
			Myelitis	1	0
		Dental and oral soft tissue infections	Gingivitis	1	0
			Parotitis	1	0
		Ear infections	Ear infection	1	0
			Labyrinthitis	3	0
			Otitis media acute	1	0
		Eye and eyelid infections	Conjunctivitis	3	0
		Infections NEC	Abscess	2	0
			Infection	1	0
			Respiratory tract infection	1	0
		Lower respiratory tract and lung infections	Bronchitis	1	0
			Lower respiratory tract infection	2	0
			Pneumonia	2	0
		Male reproductive tract infections	Orchitis	1	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Neutropenic sepsis	1	0
			Sepsis	1	0
			Urosepsis	1	1
		Skin structures and soft tissue infections	Eczema infected	1	0
			Rash pustular	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Upper respiratory tract infections	Epiglottitis	1	0
			Nasopharyngitis	3	0
			Pharyngitis	1	0
			Rhinitis	2	0
			Tonsillitis	2	0
			Upper respiratory tract infection	4	0
	Mycobacterial infectious disorders	Tuberculous infections	Erythema induratum	4	0
	Viral infectious disorders	Adenoviral infections	Adenovirus infection	1	0
		Arenaviral infections	Choriomeningitis lymphocytic	1	0
		Coronavirus infections	COVID-19	2	0
		Cytomegaloviral infections	Cytomegalovirus infection	1	0
		Epstein-Barr viral infections	Epstein-Barr virus infection	2	0
			Hepatitis infectious mononucleosis	1	0
			Infectious mononucleosis	1	0
		Flaviviral infections	Dengue fever	1	0
		Hepatitis virus infections	Hepatitis A	20	0
		Herpes viral infections	Herpes simplex	1	0
			Herpes zoster	4	0
			Human herpesvirus 6 infection	2	0
			Oral herpes	1	0
			Varicella zoster virus infection	1	0
		Influenza viral infections	Influenza	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Mumps viral infections	Mumps	1	0
		Respiratory syncytial viral infections	Respiratory syncytial virus infection	1	0
		Rubella viral infections	Rubella	1	0
		Rubeola viral infections	Measles	1	0
		Viral infections NEC	Encephalitis viral	1	0
			Gianotti-Crosti syndrome	1	0
			Hepatitis viral	1	0
			Sweating fever	1	0
			Viral infection	3	0
	Total			119	1
Injury, poisoning and procedural complications	Bone and joint injuries	Fractures and dislocations NEC	Joint dislocation	1	0
	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	2	0
			Maternal exposure before pregnancy	1	0
	Injuries NEC	Muscle, tendon and ligament injuries	Muscle injury	1	0
		Non-site specific injuries NEC	Fall	6	0
			Foreign body	1	0
			Wound haemorrhage	1	0
			Wound secretion	1	0
		Site specific injuries NEC	Head injury	2	0
		Skin injuries NEC	Contusion	6	0
			Skin laceration	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	4	0
			Wrong technique in product usage process	1	0
		Product administration errors and issues	Accidental overdose	5	0
			Expired product administered	2	0
			Extra dose administered	2	0
			Inappropriate schedule of product administration	1	0
			Incomplete course of vaccination	2	0
			Incorrect dose administered	2	0
			Product administered to patient of inappropriate age	1	0
			Product administration error	1	0
			Wrong product administered	1	0
		Product selection errors and issues	Product selection error	1	0
		Product storage errors and issues in the product use system	Product storage error	3	0
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	3	0
	Procedural related injuries and complications NEC	Vaccination related complications	Immunisation reaction	1	0
			Post vaccination syndrome	1	0
	Total			54	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	ECG investigations	Electrocardiogram abnormal	1	0
		Heart rate and pulse investigations	Heart rate decreased	5	0
			Heart rate increased	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Heart rate irregular	2	0
			Pulse abnormal	3	0
			Pulse absent	1	0
			Radial pulse abnormal	1	0
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	12	0
			Blood pressure increased	2	0
	Cytogenetic investigations and genetic analyses	Cell marker analyses	Carbohydrate antigen 19-9 increased	1	0
	Enzyme investigations NEC	Tissue enzyme analyses NEC	Blood alkaline phosphatase increased	3	0
	Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	Fibrin D dimer increased	1	0
			International normalised ratio increased	2	0
		Haematological analyses NEC	Red blood cell sedimentation rate increased	4	0
		Platelet analyses	Platelet count decreased	3	0
			Platelet count increased	1	0
		Red blood cell analyses	Haemoglobin decreased	1	0
		White blood cell analyses	Neutrophil count decreased	1	0
			White blood cell count decreased	2	0
			White blood cell count increased	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase abnormal	1	0
			Alanine aminotransferase increased	6	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG T Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Aspartate aminotransferase increased	4	0
			Blood bilirubin increased	4	0
			Gamma-glutamyltransferase increased	7	0
			Hepatic enzyme abnormal	1	0
			Hepatic enzyme increased	8	0
			Liver function test abnormal	24	0
			Liver function test increased	9	0
	Immunology and allergy investigations	Autoimmunity analyses	Smooth muscle antibody positive	1	0
	Investigations, imaging and histopathology procedures NEC	Imaging procedures NEC	Magnetic resonance imaging abnormal	1	0
	Lipid analyses	Lipoprotein and lipid tests NEC	Lipids increased	1	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	2	0
	Microbiology and serology investigations	Virus identification and serology	Hepatitis A antibody positive	1	0
	Neurological, special senses and psychiatric investigations	Neurologic diagnostic procedures	Electroencephalogram abnormal	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature fluctuation	1	0
			Body temperature increased	19	0
			General physical condition abnormal	1	0
			Weight decreased	7	0
			Weight increased	1	0
	Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein increased	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Protein total decreased	1	0
	Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood urea increased	1	0
		Urinalysis NEC	Urine analysis abnormal	1	0
	Toxicology and therapeutic drug monitoring	Toxicology laboratory analyses	Blood aluminium increased	1	0
	Total			154	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	49	0
			Increased appetite	1	0
	Bone, calcium, magnesium and phosphorus metabolism disorders	Calcium metabolism disorders	Tetany	1	0
	Electrolyte and fluid balance conditions	Total fluid volume decreased	Dehydration	2	0
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Alcohol intolerance	2	0
			Food intolerance	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Diabetes mellitus	2	0
			Diabetes mellitus inadequate control	1	0
			Type 1 diabetes mellitus	2	0
		Hypoglycaemic conditions NEC	Hypoglycaemia	1	0
			Hypoglycaemia neonatal	1	0
	Lipid metabolism disorders	Hyperlipidaemias NEC	Hyperlipidaemia	1	0
	Total			64	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Bone pain	1	0
			Pain in jaw	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Myofascitis	1	0
	Joint disorders	Arthropathies NEC	Arthritis	4	0
			Arthropathy	6	0
			Polyarthritis	4	0
			Seronegative arthritis	2	0
		Joint related disorders NEC	Periarthritis	5	0
		Joint related signs and symptoms	Arthralgia	72	0
			Joint stiffness	3	0
			Joint swelling	11	0
		Osteoarthropathies	Osteoarthritis	1	0
		Rheumatoid arthropathies	Juvenile idiopathic arthritis	1	0
			Rheumatoid arthritis	3	0
		Spondyloarthropathies	Arthritis reactive	2	0
	Muscle disorders	Muscle infections and inflammations	Dermatomyositis	1	0
			Myositis	1	0
		Muscle pains	Fibromyalgia	1	0
			Myalgia	57	0
		Muscle related signs and symptoms NEC	Muscle atrophy	3	0
			Muscle disorder	1	0
			Muscle fatigue	2	0
			Muscle spasms	7	0
			Muscle tightness	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Muscle twitching	7	0
		Muscle tone abnormalities	Floppy infant	1	0
			Muscle rigidity	3	0
			Torticollis	1	0
			Trismus	1	0
		Muscle weakness conditions	Muscular weakness	19	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal stiffness	19	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	13	0
			Limb discomfort	8	0
			Musculoskeletal chest pain	1	0
			Neck pain	11	0
			Pain in extremity	51	0
	Synovial and bursal disorders	Bursal disorders	Bursitis	3	0
		Synovial disorders	Synovitis	1	0
	Total			330	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemias	Leukaemias myeloid NEC	Myeloid leukaemia	1	0
		Leukaemias NEC	Leukaemia	1	0
	Miscellaneous and site unspecified neoplasms malignant and unspecified	Neoplasms unspecified malignancy and site unspecified NEC	Neoplasm	1	0
	Reproductive neoplasms female benign	Reproductive neoplasms female benign NEC	Benign hydatidiform mole	1	0
	Skin neoplasms malignant and unspecified	Skin melanomas (excl ocular)	Malignant melanoma	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Skin neoplasms malignant and unspecified (excl melanoma)	Basal cell carcinoma	1	0
			Neoplasm skin	2	0
	Total			9	0
Nervous system disorders	Central nervous system infections and inflammations	Myelitis (incl infective)	Myelitis transverse	8	0
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebrovascular accident	2	0
			Subarachnoid haemorrhage	1	0
		Transient cerebrovascular events	Transient ischaemic attack	2	0
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	7	0
			Facial paralysis	4	0
		Mixed cranial nerve disorders	Bulbar palsy	1	0
		Optic nerve disorders NEC	Optic neuritis	2	0
	Demyelinating disorders	Demyelinating disorders NEC	Acute disseminated encephalomyelitis	3	0
			Demyelination	1	0
			Myelin oligodendrocyte glycoprotein antibody-associated disease	1	0
	Encephalopathies	Encephalopathies NEC	Encephalopathy	1	0
	Headaches	Headaches NEC	Headache	164	0
			Sinus headache	1	0
		Migraine headaches	Hemiplegic migraine	1	0
			Migraine	3	0
	Increased intracranial pressure and hydrocephalus	Hydrocephalic conditions	Hydrocephalus	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Mental impairment disorders	Increased intracranial pressure disorders	Brain oedema	2	2
		Memory loss (excl dementia)	Amnesia	4	0
			Memory impairment	1	0
		Mental impairment (excl dementia and memory loss)	Cognitive disorder	2	0
			Disturbance in attention	2	0
			Judgement impaired	1	0
			Mental impairment	1	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Clumsiness	1	0
			Dyskinesia	10	0
			Movement disorder	1	0
		Paralysis and paresis (excl cranial nerve)	Hemiparesis	2	0
			Hemiplegia	1	0
			Monoplegia	2	0
			Paralysis	4	0
		Tremor (excl congenital)	Tremor	26	0
	Neurological disorders NEC	Abnormal reflexes	Reflexes abnormal	1	0
		Coma states	Coma	1	0
		Coordination and balance disturbances	Ataxia	1	0
			Balance disorder	6	0
			Coordination abnormal	2	0
			Dysstasia	1	0
			Nystagmus	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Cortical dysfunction NEC	Aphasia	3	0
		Disturbances in consciousness NEC	Altered state of consciousness	2	0
			Lethargy	42	0
			Loss of consciousness	27	0
			Somnolence	16	0
			Syncope	115	0
		Nervous system disorders NEC	Nervous system disorder	2	0
			Neurodegenerative disorder	1	0
		Neurological signs and symptoms NEC	Brain fog	1	0
			Dizziness	93	0
			Dizziness postural	1	0
			Drooling	1	0
			Head discomfort	1	0
			Meningism	1	0
			Myoclonus	1	0
			Presyncope	23	0
			Tongue biting	2	0
			Unresponsive to stimuli	10	0
		Paraesthesias and dysaesthesias	Burning sensation	2	0
			Dysaesthesia	1	0
			Hyperaesthesia	2	0
			Hypoaesthesia	17	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Paraesthesia	39	0
			Paraesthesia mucosal	2	0
		Sensory abnormalities NEC	Ageusia	1	0
			Dysgeusia	4	0
			Neuralgia	3	0
			Sensory disturbance	6	0
			Sensory loss	1	0
			Taste disorder	1	0
		Speech and language abnormalities	Dysarthria	3	0
			Speech disorder	2	0
	Neurological disorders of the eye	Neurologic visual problems NEC	Hemianopia	1	0
			Tunnel vision	1	0
	Neuromuscular disorders	Motor neurone diseases	Motor neurone disease	1	0
		Muscle tone abnormal	Hypotonia	7	0
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	1	0
			Muscle contractions involuntary	1	0
			Neuromyopathy	1	0
		Neuromuscular junction dysfunction	Myasthenia gravis	1	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	9	0
		Chronic polyneuropathies	Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
		Mononeuropathies	Peroneal nerve palsy	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Radial nerve palsy	2	0
			Sciatic nerve palsy	1	0
		Peripheral neuropathies NEC	Neuralgic amyotrophy	4	0
			Neuropathy peripheral	5	0
			Peripheral motor neuropathy	1	0
			Peripheral sensorimotor neuropathy	1	0
			Peripheral sensory neuropathy	1	0
			Polyneuropathy	2	0
	Seizures (incl subtypes)	Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	4	0
		Seizures and seizure disorders NEC	Epilepsy	10	2
			Febrile convulsion	2	0
			Psychogenic seizure	1	0
			Seizure	42	0
			Seizure anoxic	1	0
			Tonic convulsion	2	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	1	0
			Narcolepsy	1	0
	Spinal cord and nerve root disorders	Lumbar spinal cord and nerve root disorders	Sciatica	1	0
		Spinal cord and nerve root disorders NEC	Brown-Sequard syndrome	1	0
			Radiculopathy	4	0
			Spinal cord disorder	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Thoracic spinal cord and nerve root disorders	Thoracic radiculopathy	1	0
	Total			816	4
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions not specified as induced or spontaneous	Abortion incomplete	1	0
		Abortions spontaneous	Abortion spontaneous	11	0
			Abortion threatened	1	0
		Stillbirth and foetal death	Stillbirth	1	1
	Foetal complications	Foetal complications NEC	Foetal distress syndrome	1	0
	Maternal complications of labour and delivery	Maternal complications of delivery NEC	Retained placenta or membranes	2	0
	Maternal complications of pregnancy	Hypertension associated disorders of pregnancy	Pre-eclampsia	2	0
		Maternal complications of pregnancy NEC	Ectopic pregnancy	2	0
	Neonatal and perinatal conditions	Gestational age and weight conditions	Premature baby	5	0
		Neonatal hepatobiliary disorders	Jaundice neonatal	1	0
	Postpartum and puerperal disorders	Postpartum complications NEC	Postpartum haemorrhage	1	0
	Pregnancy, labour, delivery and postpartum conditions	Normal pregnancy, labour and delivery	Live birth	1	0
	Total			29	1
Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Manufacturing laboratory controls issues	Out of specification test results	1	0
		Product quality issues NEC	Product quality issue	1	0
	Total			2	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Anxiety	6	0
			Nervousness	2	0
			Tension	1	0
		Fear symptoms and phobic disorders (incl social phobia)	Fear	1	0
		Panic attacks and disorders	Panic attack	3	0
			Panic reaction	3	0
	Changes in physical activity	Decreased physical activity levels	Catatonia	1	0
		Stereotypies and automatisms	Bruxism	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	5	0
			Disorientation	8	0
		Deliria	Delirium	1	0
	Depressed mood disorders and disturbances	Depressive disorders	Depression	8	0
		Mood alterations with depressive symptoms	Depressed mood	1	0
			Tearfulness	2	0
	Dissociative disorders	Dissociative states	Dissociative disorder	1	0
	Disturbances in thinking and perception	Delusional symptoms	Delusion	1	0
		Hallucinations (excl sleep-related)	Hallucination	4	0
			Hallucinations, mixed	1	0
		Thinking disturbances	Bradyphrenia	1	0
	Eating disorders and disturbances	Eating disorders NEC	Eating disorder	2	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Euphoric mood	1	0
			Irritability	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Fluctuating mood symptoms	Mood swings	1	0
		Mood disorders NEC	Listless	3	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Paranoia	1	0
			Personality change	1	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Staring	1	0
	Psychiatric disorders NEC	Mental disorders NEC	Mental disorder	2	0
	Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Acute psychosis	1	0
			Psychotic behaviour	1	0
			Psychotic disorder	2	0
		Schizophrenia NEC	Schizophrenia	2	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	6	0
			Middle insomnia	1	0
		Parasomnias	Abnormal dreams	2	0
			Nightmare	2	0
		Sleep disorders NEC	Sleep disorder	2	0
	Total			86	0
Renal and urinary disorders	Bladder and bladder neck disorders (excl calculi)	Bladder disorders NEC	Bladder disorder	1	0
		Myoneurogenic bladder disorders	Hypertonic bladder	1	0
	Nephropathies	Glomerulonephritis and nephrotic syndrome	Glomerulonephritis acute	1	0
			Glomerulonephritis membranous	1	0
			IgA nephropathy	1	0
		Nephritis NEC	Tubulointerstitial nephritis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
			Anuria	1	0
			Oliguria	1	0
			Renal impairment	1	0
		Renal obstructive disorders	Hydronephrosis	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Incontinence	3	0
			Micturition disorder	1	0
			Pollakiuria	1	0
			Urinary incontinence	4	0
		Urinary abnormalities	Chromaturia	8	0
			Glycosuria	2	0
			Haematuria	3	0
			Proteinuria	2	0
		Urinary tract signs and symptoms NEC	Renal colic	1	0
	Total			36	0
Reproductive system and breast disorders	Breast disorders	Breast disorders NEC	Retracted nipple	2	0
	Menstrual cycle and uterine bleeding disorders	Menstruation with increased bleeding	Heavy menstrual bleeding	2	0
	Penile and scrotal disorders (excl infections and inflammations)	Penile disorders NEC (excl erection and ejaculation)	Penis disorder	2	0
	Sexual function and fertility disorders	Erection and ejaculation conditions and disorders	Erectile dysfunction	2	0
	Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular disorder	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Testicular swelling	2	0
	Total			11	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	2	0
			Bronchospasm	3	0
			Wheezing	9	0
	Lower respiratory tract disorders (excl obstruction and infection)	Lower respiratory tract inflammatory and immunologic conditions	Pneumonitis	1	0
			Interstitial lung disease	1	0
			Acute respiratory distress syndrome	1	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Neonatal respiratory distress syndrome	2	0
	Pleural disorders	Pneumothorax and pleural effusions NEC	Pleural effusion	3	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	1	0
			Dyspnoea	19	0
			Grunting	2	0
			Hyperventilation	1	0
			Hypopnoea	1	0
			Respiration abnormal	2	0
			Respiratory arrest	1	0
			Respiratory distress	3	0
			Sleep apnoea syndrome	2	0
			Tachypnoea	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Conditions associated with abnormal gas exchange	Hypoxia	1	0
		Coughing and associated symptoms	Cough	13	0
			Haemoptysis	1	0
		Respiratory failures (excl neonatal)	Acute respiratory failure	1	0
			Respiratory failure	1	1
		Respiratory tract disorders NEC	Respiratory disorder	1	0
			Respiratory tract oedema	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Pleuritic pain	1	0
		Upper respiratory tract signs and symptoms	Oropharyngeal pain	22	0
			Rhinorrhoea	1	0
			Sneezing	4	0
			Throat tightness	3	0
			Yawning	1	0
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Stridor	4	0
		Nasal disorders NEC	Epistaxis	1	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal erythema	1	0
			Pharyngeal inflammation	1	0
			Pharyngeal swelling	2	0
			Pharyngeal ulceration	1	0
			Tonsillar erythema	1	0
	Total			117	1

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	15	0
		Urticarias	Urticaria	122	0
			Urticaria papular	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	8	0
			Blister rupture	1	0
			Blood blister	2	0
			Dermatitis bullous	1	0
			Erythema multiforme	12	0
			Pemphigoid	1	0
		Dermal and epidermal conditions NEC	Dry skin	1	0
			Papule	2	0
			Scab	2	0
			Skin burning sensation	2	0
			Skin discolouration	9	0
			Skin lesion	4	0
			Skin plaque	1	0
			Skin reaction	3	0
			Yellow skin	3	0
		Dermatitis and eczema	Dermatitis allergic	8	0
			Eczema	10	0
			Eczema nummular	1	0
		Dermatitis ascribed to specific agent	Drug eruption	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Toxic skin eruption	1	0
		Erythemas	Erythema	30	0
		Exfoliative conditions	Skin exfoliation	3	0
		Papulosquamous conditions	Erythema annulare	1	0
			Lichen planus	1	0
		Photosensitivity and photodermatitis conditions	Photosensitivity reaction	4	0
		Pruritus NEC	Pruritus	45	0
		Psoriatic conditions	Guttate psoriasis	1	0
		Pustular conditions	Acute generalised exanthematous pustulosis	1	0
		Rashes, eruptions and exanthems NEC	Rash	102	0
			Rash erythematous	27	0
			Rash macular	25	0
			Rash maculo-papular	11	0
			Rash morbilliform	4	0
			Rash papular	6	0
			Rash pruritic	25	0
			Rash rubelliform	1	0
			Rash vesicular	2	0
	Skin and subcutaneous tissue disorders NEC	Panniculitides	Erythema nodosum	2	0
		Skin and subcutaneous conditions NEC	Skin mass	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Skin appendage conditions	Skin and subcutaneous tissue ulcerations	Skin ulcer	1	0
		Alopecias	Alopecia	1	0
		Apocrine and eccrine gland disorders	Cold sweat	19	0
			Hyperhidrosis	49	0
			Miliaria	1	0
			Night sweats	6	0
	Skin vascular abnormalities	Purpura and related conditions	Henoch-Schonlein purpura	1	0
			Petechiae	2	0
			Purpura	5	0
		Skin vasculitides	Cutaneous vasculitis	1	0
			Vasculitic rash	3	0
		Skin vasomotor conditions	Livedo reticularis	1	0
		Telangiectasia and related conditions	Spider naevus	1	0
	Total			594	0
Social circumstances	Lifestyle issues	Disability issues	Immobile	1	0
			Impaired driving ability	1	0
			Impaired work ability	1	0
			Loss of personal independence in daily activities	1	0
			Wheelchair user	1	0
	Total			5	0
Surgical and medical procedures	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Interchange of vaccine products	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Total			1	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	1	0
			Raynaud's phenomenon	2	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	18	0
			Peripheral circulatory failure	1	0
			Shock	1	0
		Vascular hypotensive disorders	Hypotension	23	0
			Orthostatic hypotension	1	0
	Embolism and thrombosis	Peripheral embolism and thrombosis	Thrombophlebitis	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	7	0
			Flushing	11	0
			Hot flush	5	0
		Site specific vascular disorders NEC	Pallor	48	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	2	0
	Vascular infections and inflammations	Arterial infections and inflammations	Giant cell arteritis	1	0
		Vasculitides NEC	Vasculitis	1	0
	Total			124	0
Total				4,370	11

Number of ADR Reports

1,723