

Typhoid Vaccine Analysis Print.

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

Report run: 06/05/2025

Earliest reaction date: 11/10/1965

Reaction MedDRA SOC Name	Reaction MedDRA HLGT 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	0
	Haemolyses and related conditions	Anaemias haemolytic NEC	Haemolytic anaemia	1	0
	Platelet disorders	Platelet disorders NEC	Platelet disorder	1	0
		Thrombocytopenias	Immune thrombocytopenia	3	0
			Thrombocytopenia	3	0
			Thrombocytopenic purpura	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	1	0
			Lymphadenopathy	19	0
		Spleen disorders	Splenomegaly	1	0
	White blood cell disorders	Leukocytoses NEC	Leukocytosis	1	0
		Leukopenias NEC	Lymphopenia	1	0
		Neutropenias	Neutropenia	3	0
	Total			38	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	16	0
			Extrasystoles	1	0
			Tachycardia	13	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	5	0
	Coronary artery disorders	Coronary artery disorders NEC	Coronary artery disease	1	0
	Heart failures	Heart failures NEC	Cardiac failure	1	0
			Ventricular failure	1	0
	Myocardial disorders	Myocardial disorders NEC	Left ventricular dysfunction	1	0
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	3	0
		Pericardial disorders NEC	Pericardial effusion	1	0
	Total			44	0
Congenital, familial and genetic disorders	Cardiac and vascular disorders congenital	Cardiac septal defects congenital	Atrial septal defect	1	0
			Ventricular septal defect	1	0
	Chromosomal abnormalities, gene alterations and gene variants	Autosomal chromosomal abnormalities	Trisomy 21	1	0
	Eye disorders congenital	Lens disorders congenital	Lens abnormality, congenital	1	0
		Ocular disorders congenital NEC	Microphthalmos	1	0
	Gastrointestinal tract disorders congenital	Oesophageal disorders congenital	Oesophageal atresia	1	0
		Oral cavity disorders congenital NEC	Tethered oral tissue	1	0
	Musculoskeletal and connective tissue disorders congenital	Musculoskeletal and connective tissue disorders of limbs congenital	Polydactyly	1	0
			Syndactyly	2	0
			Talipes	1	0
		Musculoskeletal disorders congenital NEC	Congenital musculoskeletal disorder	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Neurological disorders congenital	Cerebral disorders congenital	Congenital brain damage	1	0
	Respiratory disorders congenital	Laryngeal and tracheal disorders congenital	Tracheo-oesophageal fistula	1	0
		Respiratory tract disorders congenital NEC	Respiratory tract malformation	1	0
	Total			15	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	3	0
			Ear swelling	1	0
	Hearing disorders	Hearing losses	Deafness	3	0
			Deafness neurosensory	1	0
			Hypoacusis	2	0
			Sudden hearing loss	1	0
		Hyperacusia	Hyperacusis	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	7	0
			Vertigo	12	0
			Vertigo positional	1	0
	Total			32	0
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye disorder	1	0
			Eye pain	2	0
			Eye swelling	6	0
			Periorbital oedema	5	0
	Ocular infections, irritations and inflammations	Conjunctival infections, irritations and inflammations	Conjunctivitis allergic	1	0

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		Iris and uveal tract infections, irritations and inflammations	Iridocyclitis	1	0
		Lid, lash and lacrimal infections, irritations and inflammations	Swelling of eyelid	3	0
		Ocular infections, inflammations and associated manifestations	Eye pruritus	2	0
			Ocular hyperaemia	1	0
	Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	7	0
			Oculogyric crisis	2	0
		Pupil disorders	Mydriasis	4	0
			Pupil fixed	2	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Photophobia	13	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	Refractive and accommodative disorders	Accommodation disorder	1	0
		Visual colour distortions	Chromatopsia	1	0
		Visual disorders NEC	Diplopia	2	0
			Vision blurred	15	0
		Visual impairment and blindness (excl colour blindness)	Blindness	2	0
			Visual acuity reduced	1	0
			Visual impairment	10	0
	Total			84	0
Gastrointestinal disorders	Anal and rectal conditions NEC	Anal and rectal disorders NEC	Rectal prolapse	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Exocrine pancreas conditions	Acute and chronic pancreatitis	Pancreatitis	2	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Functional gastrointestinal disorder	2	0
			Gastrointestinal disorder	7	0
	Gastrointestinal haemorrhages NEC	Intestinal haemorrhages	Rectal haemorrhage	3	0
		Non-site specific gastrointestinal haemorrhages	Haematemesis	3	0
			Haematochezia	4	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis ulcerative	1	0
		Gastritis (excl infective)	Gastritis	1	0
		Gastrointestinal inflammatory disorders NEC	Enterocolitis	2	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	102	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	1	0
			Gastric dilatation	2	0
			Gastrooesophageal reflux disease	2	0
		Gastrointestinal spastic and hypermotility disorders	Frequent bowel movements	2	0
			Irritable bowel syndrome	3	0
			Oesophageal spasm	2	0
	Gastrointestinal signs and symptoms	Abdominal findings abnormal	Gastrointestinal sounds abnormal	1	0
		Dyspeptic signs and symptoms	Dyspepsia	2	0
			Eructation	2	0
		Faecal abnormalities NEC	Faeces discoloured	2	0

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			Faeces pale	1	0
			Mucous stools	1	0
		Flatulence, bloating and distension	Abdominal distension	7	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	75	0
			Abdominal pain lower	3	0
			Abdominal pain upper	30	0
			Abdominal tenderness	1	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	8	0
			Dysphagia	1	0
		Nausea and vomiting symptoms	Nausea	165	0
			Regurgitation	1	0
			Retching	1	0
			Vomiting	175	0
			Vomiting projectile	3	0
	Gastrointestinal ulceration and perforation	Gastric ulcers and perforation	Gastric perforation	1	0
	Gastrointestinal vascular conditions	Haemorrhoids and gastrointestinal varices (excl oesophageal)	Haemorrhoids	1	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Chapped lips	1	0
			Cheilitis	1	0
		Oral soft tissue signs and symptoms	Lip erythema	1	0
			Oral mucosal blistering	1	0
			Oral pain	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Paraesthesia oral	4	0
		Oral soft tissue swelling and oedema	Lip swelling	16	0
			Mouth swelling	2	0
		Stomatitis and ulceration	Aphthous ulcer	1	0
			Lip ulceration	1	0
			Mouth ulceration	5	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	2	0
	Tongue conditions	Tongue signs and symptoms	Tongue coated	1	0
			Tongue movement disturbance	1	0
	Total			661	0
General disorders and administration site conditions	Administration site reactions	Injection site reactions	Injected limb mobility decreased	1	0
			Injection site atrophy	1	0
			Injection site erythema	1	0
			Injection site hypoaesthesia	1	0
			Injection site induration	1	0
			Injection site inflammation	15	0
			Injection site mass	1	0
			Injection site pain	40	0
			Injection site pruritus	2	0
			Injection site rash	1	0

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			Injection site reaction	110	0
			Injection site swelling	3	0
		Vaccination site reactions	Vaccination site mass	2	0
			Vaccination site movement impairment	1	0
			Vaccination site pain	6	0
			Vaccination site reaction	1	0
			Vaccination site swelling	2	0
			Vaccination site warmth	1	0
	Body temperature conditions	Febrile disorders	Hyperpyrexia	5	1
			Pyrexia	310	0
	Fatal outcomes	Death and sudden death	Sudden death	3	3
	General system disorders NEC	Adverse effect absent	No adverse event	1	0
		Asthenic conditions	Asthenia	33	0
			Chronic fatigue syndrome	6	0
			Fatigue	65	0
			Malaise	165	0
		Feelings and sensations NEC	Chills	123	0
			Feeling abnormal	8	0
			Feeling cold	5	0
			Feeling hot	20	0
			Feeling of body temperature change	6	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Hangover	1	0
			Hunger	1	0
			Thirst	2	0
		Gait disturbances	Gait disturbance	6	0
		General signs and symptoms NEC	Condition aggravated	5	0
			Crying	1	0
			Effusion	1	0
			General physical health deterioration	1	0
			Glassy eyes	1	0
			Illness	7	0
			Induration	1	0
			Influenza like illness	60	0
			Local reaction	19	0
			Multiple organ dysfunction syndrome	1	0
			Peripheral swelling	25	0
			Screaming	4	0
			Sensitivity to weather change	1	0
			Swelling	13	0
			Swelling face	22	0
			Unevaluable event	1	0
		Inflammatons	Inflammation	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Oedema NEC	Face oedema	5	0
			Generalised oedema	1	0
			Gravitational oedema	2	0
			Oedema	19	0
			Oedema peripheral	10	0
		Pain and discomfort NEC	Chest discomfort	8	0
			Chest pain	27	0
			Discomfort	3	0
			Pain	50	0
			Suprapubic pain	1	0
			Tenderness	3	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	1	0
			Potentiating drug interaction	2	0
		Therapeutic and nontherapeutic responses	Adverse reaction	1	0
			Drug ineffective	6	0
			Vaccination failure	14	0
	Tissue disorders NEC	Mass conditions NEC	Cyst	1	0
			Mass	1	0
	Total			1,271	4
Hepatobiliary disorders	Gallbladder disorders	Cholecystitis and cholelithiasis	Cholecystitis	1	0
			Cholelithiasis	1	0
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	11	0

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		Hepatic enzymes and function abnormalities	Hepatic function abnormal	2	0
		Hepatic failure and associated disorders	Acute hepatic failure	1	0
			Hepatic failure	1	0
		Hepatobiliary signs and symptoms	Liver tenderness	1	0
		Hepatocellular damage and hepatitis NEC	Hepatitis	3	0
			Hepatitis acute	1	0
	Total			22	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	35	0
			Serum sickness	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	2	0
			Food allergy	1	0
			Milk allergy	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	72	0
			Anaphylactic shock	8	0
			Anaphylactoid reaction	26	0
	Immune disorders NEC	Immune and associated conditions NEC	Haemophagocytic lymphohistiocytosis	1	1
	Total			147	1
Infections and infestations	Ancillary infectious topics	Infectious transmissions	Infection via vaccinee	1	0
	Bacterial infectious disorders	Bacterial infections NEC	Cellulitis	9	0
		Salmonella infections	Osteomyelitis salmonella	1	0
			Typhoid fever	34	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Infections - pathogen unspecified	Staphylococcal infections	Furuncle	2	0
		Abdominal and gastrointestinal infections	Gastroenteritis	4	0
		Central nervous system and spinal infections	Brain abscess	1	0
			Encephalitis	4	0
			Myelitis	7	0
		Ear infections	Labyrinthitis	3	0
		Eye and eyelid infections	Conjunctivitis	4	0
		Infections NEC	Abscess	1	0
			Infection	2	0
			Injection site abscess	5	0
			Localised infection	1	0
			Respiratory tract infection	1	0
		Lower respiratory tract and lung infections	Lower respiratory tract infection	1	0
			Pneumonia	1	0
		Male reproductive tract infections	Orchitis	1	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Septic shock	1	0
		Skin structures and soft tissue infections	Pustule	1	0
			Rash pustular	2	0
		Upper respiratory tract infections	Nasopharyngitis	6	0
			Pharyngitis	3	0
			Rhinitis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Tonsillitis	1	0
			Upper respiratory tract infection	3	0
		Urinary tract infections	Pyelonephritis	1	0
			Urinary tract infection	1	0
		Vascular infections	Lymphangitis	1	0
	Mycobacterial infectious disorders	Tuberculous infections	Erythema induratum	1	0
	Protozoal infectious disorders	Amoebic infections	Amoebic dysentery	1	0
	Viral infectious disorders	Arenaviral infections	Choriomeningitis lymphocytic	1	0
		Caliciviral infections	Gastroenteritis norovirus	1	0
		Coronavirus infections	COVID-19	1	0
		Flaviviral infections	Yellow fever vaccine-associated viscerotropic disease	1	0
		Herpes viral infections	Herpes simplex	3	0
			Herpes zoster	3	0
		Influenza viral infections	Influenza	1	0
		Viral infections NEC	Encephalitis viral	1	0
	Total			118	0
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	5	0
			Foetal exposure during pregnancy	1	0
			Maternal exposure before pregnancy	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Injuries NEC		Maternal exposure timing unspecified	1	0
		Cerebral injuries NEC	Subdural haemorrhage	1	0
		Muscle, tendon and ligament injuries	Muscle injury	1	0
		Non-site specific injuries NEC	Fall	3	0
			Foreign body	2	0
			Wound haemorrhage	1	0
			Wound secretion	1	0
		Site specific injuries NEC	Head injury	1	0
		Skin injuries NEC	Contusion	3	0
			Scar	1	0
			Skin laceration	1	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Wrong technique in product usage process	3	0
		Product administration errors and issues	Expired product administered	1	0
			Extra dose administered	1	0
			Inappropriate schedule of product administration	6	0
			Incorrect dose administered	1	0
			Poor quality product administered	1	0
			Product administered at inappropriate site	1	0
			Product administration error	3	0
		Product preparation errors and issues	Product preparation error	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Product storage errors and issues in the product use system	Product storage error	1	0
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	1	0
	Total			45	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	ECG investigations	Electrocardiogram abnormal	1	0
			Electrocardiogram ST-T change	1	0
		Heart rate and pulse investigations	Heart rate decreased	2	0
			Heart rate increased	6	0
			Pulse abnormal	4	0
			Radial pulse abnormal	1	0
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	5	0
			Blood pressure increased	1	0
	Enzyme investigations NEC	Skeletal and cardiac muscle analyses	Blood creatine phosphokinase increased	3	0
	Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	International normalised ratio increased	2	0
		Haematological analyses NEC	Red blood cell sedimentation rate increased	3	0
		White blood cell analyses	Lymphocyte morphology abnormal	1	0
			Neutrophil count abnormal	1	0
			Neutrophil toxic granulation present	1	0
			White blood cell count increased	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	2	0
			Hepatic enzyme increased	1	0
			Liver function test abnormal	3	0
	Investigations, imaging and histopathology procedures NEC	Imaging procedures NEC	Magnetic resonance imaging abnormal	1	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen consumption increased	1	0
		Carbohydrate tolerance analyses (incl diabetes)	Blood glucose decreased	1	0
	Microbiology and serology investigations	Microbiology and serology tests NEC	Serology positive	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature	1	0
			Body temperature fluctuation	2	0
			Body temperature increased	12	0
			General physical condition abnormal	1	0
			Spleen palpable	1	0
			Weight decreased	4	0
	Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein increased	3	0
	Total			68	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	22	0
		General nutritional disorders NEC	Abnormal loss of weight	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	7	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Type 2 diabetes mellitus	1	0
		Hyperglycaemic conditions NEC	Glucose tolerance impaired	1	0
		Hypoglycaemic conditions NEC	Hypoglycaemia neonatal	1	0
	Total			34	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Pain in jaw	1	0
	Joint disorders	Arthropathies NEC	Arthritis	8	0
			Arthropathy	3	0
			Polyarthritis	1	0
			Seronegative arthritis	1	0
		Joint related disorders NEC	Periarthritis	1	0
			Rotator cuff syndrome	1	0
		Joint related signs and symptoms	Arthralgia	51	0
			Joint stiffness	2	0
			Joint swelling	8	0
		Rheumatoid arthropathies	Rheumatoid arthritis	2	0
		Spondyloarthropathies	Arthritis reactive	3	0
	Muscle disorders	Muscle infections and inflammations	Dermatomyositis	1	0
			Myositis	1	0
			Polymyositis	1	0
		Muscle pains	Myalgia	76	0
		Muscle related signs and symptoms NEC	Muscle atrophy	1	0
			Muscle spasms	10	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Muscle tightness	1	0
			Muscle twitching	6	0
		Muscle tone abnormalities	Muscle rigidity	2	0
			Torticollis	1	0
		Muscle weakness conditions	Muscular weakness	14	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Limb mass	1	0
			Musculoskeletal stiffness	19	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	15	0
			Limb discomfort	4	0
			Neck pain	10	0
			Pain in extremity	52	0
		Soft tissue disorders NEC	Groin pain	1	0
	Synovial and bursal disorders	Bursal disorders	Bursitis	2	0
	Total			300	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cutaneous neoplasms benign	Skin neoplasms benign	Acrochordon	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	1	0
			Basal cell carcinoma	1	0
		Skin neoplasms malignant and unspecified (excl melanoma)	Neoplasm skin	1	0
	Total			6	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Nervous system disorders	Central nervous system infections and inflammations	Encephalitis NEC	Encephalitis autoimmune	1	0
		Myelitis (incl infective)	Myelitis transverse	7	0
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral artery thrombosis	1	0
			Cerebrovascular accident	2	0
			Subarachnoid haemorrhage	1	0
		Transient cerebrovascular events	Transient ischaemic attack	1	0
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	3	0
			Facial paralysis	2	0
		Mixed cranial nerve disorders	Bulbar palsy	2	0
		Optic nerve disorders NEC	Optic neuritis	1	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	2	0
	Headaches	Headaches NEC	Headache	232	0
		Migraine headaches	Hemiplegic migraine	1	0
			Migraine	3	0
	Increased intracranial pressure and hydrocephalus	Increased intracranial pressure disorders	Intracranial pressure increased	1	0
	Mental impairment disorders	Memory loss (excl dementia)	Amnesia	2	0
		Mental impairment (excl dementia and memory loss)	Cognitive disorder	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Judgement impaired	1	0
			Dyskinesia	7	0
			Extrapyramidal disorder	1	0
			Hypokinesia	2	0
			Movement disorder	2	0
		Dystonias	Dystonia	2	0
		Paralysis and paresis (excl cranial nerve)	Monoplegia	2	0
			Paralysis	5	0
			Paresis	1	0
		Tremor (excl congenital)	Tremor	47	0
	Neurological disorders NEC	Abnormal reflexes	Reflexes abnormal	1	0
		Coma states	Coma	1	0
		Coordination and balance disturbances	Ataxia	2	0
			Balance disorder	5	0
			Coordination abnormal	3	0
			Nystagmus	1	0
		Cortical dysfunction NEC	Aphasia	4	0
			Dyspraxia	1	0
		Disturbances in consciousness NEC	Altered state of consciousness	1	0
			Depressed level of consciousness	3	0
			Lethargy	30	0
			Loss of consciousness	25	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Somnolence	34	0
			Syncope	155	0
		Nervous system disorders NEC	Cerebral disorder	1	0
			Nervous system disorder	1	0
		Neurological signs and symptoms NEC	Brain fog	2	0
			Dizziness	119	0
			Head discomfort	1	0
			Meningism	4	0
			Myoclonus	1	0
			Presyncope	32	0
			Unresponsive to stimuli	5	0
		Paraesthesias and dysaesthesias	Burning sensation	1	0
			Formication	1	0
			Hyperaesthesia	1	0
			Hypoaesthesia	16	0
			Paraesthesia	32	0
		Sensory abnormalities NEC	Dysgeusia	2	0
			Neuralgia	1	0
			Sensory disturbance	4	0
			Sensory loss	1	0
		Speech and language abnormalities	Speech disorder	4	0
	Neurological disorders of the eye	Neurologic visual problems NEC	Hemianopia	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Tunnel vision	2	0
	Neuromuscular disorders	Motor neurone diseases	Motor neurone disease	1	0
		Muscle tone abnormal	Hypotonia	3	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	10	0
		Chronic polyneuropathies	Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
		Peripheral neuropathies NEC	Neuralgic amyotrophy	2	0
			Neuropathy peripheral	6	0
			Peripheral sensory neuropathy	1	0
			Polyneuropathy	1	0
	Seizures (incl subtypes)	Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	12	0
		Seizures and seizure disorders NEC	Epilepsy	9	2
			Febrile convulsion	8	0
			Partial seizures	1	0
			Seizure	62	0
	Spinal cord and nerve root disorders	Spinal cord and nerve root disorders NEC	Brown-Sequard syndrome	1	0
			Radiculitis brachial	1	0
			Radiculopathy	1	0
			Spinal cord disorder	1	0
	Structural brain disorders	Structural brain disorders NEC	Brain injury	1	0
			Cerebral atrophy	1	0
	Total			961	2

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions not specified as induced or spontaneous	Abortion missed	2	0
		Abortions spontaneous	Abortion spontaneous	18	0
			Abortion threatened	1	0
	Foetal complications	Foetal complications NEC	Foetal cardiac disorder	1	0
			Foetal distress syndrome	1	0
			Hydrops foetalis	1	0
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature rupture of membranes	1	0
		Maternal complications of delivery NEC	Complication of delivery	1	0
			Retained placenta or membranes	1	0
	Maternal complications of pregnancy	Hypertension associated disorders of pregnancy	Pre-eclampsia	1	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	2	0
		Unintended pregnancies	Unintended pregnancy	1	0
	Total			40	0
Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Manufacturing laboratory controls issues	Out of specification test results	13	0
		Product quality issues NEC	Product quality issue	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Total			14	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	3	0
			Anxiety	8	0
			Nervousness	4	0
		Fear symptoms and phobic disorders (incl social phobia)	Fear	1	0
		Panic attacks and disorders	Panic attack	1	0
			Panic reaction	2	0
	Changes in physical activity	Decreased physical activity levels	Catatonia	1	0
		Increased physical activity levels	Restlessness	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	13	0
			Disorientation	11	0
		Deliria	Delirium	7	0
	Depressed mood disorders and disturbances	Depressive disorders	Depression	3	0
		Mood alterations with depressive symptoms	Depressed mood	1	0
			Tearfulness	1	0
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	1	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	5	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Irritability	1	0
		Fluctuating mood symptoms	Mood swings	1	0
		Mood disorders NEC	Listless	2	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Paranoia	2	0
			Personality change	1	0
			Suspiciousness	1	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Staring	2	0
	Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Acute psychosis	2	0
			Psychotic behaviour	1	0
			Psychotic disorder	2	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	4	0
			Middle insomnia	1	0
		Sleep disorders NEC	Sleep disorder	2	0
	Total			87	0
Renal and urinary disorders	Bladder and bladder neck disorders (excl calculi)	Bladder disorders NEC	Bladder disorder	1	0
	Nephropathies	Glomerulonephritis and nephrotic syndrome	IgA nephropathy	1	0
	Renal disorders (excl nephropathies)	Renal failure and impairment	Renal failure	3	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Fowler's syndrome	1	0
			Incontinence	2	0
			Urinary incontinence	4	0
			Urinary retention	2	0
		Urinary abnormalities	Chromaturia	1	0
			Haematuria	4	0
			Proteinuria	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Urinary tract signs and symptoms NEC	Polyuria	1	0
			Renal pain	1	0
	Total			22	0
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms	Breast pain	2	0
	Menstrual cycle and uterine bleeding disorders	Menstruation and uterine bleeding NEC	Dysmenorrhoea	5	0
			Menstruation irregular	3	0
		Menstruation with increased bleeding	Heavy menstrual bleeding	4	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Pruritus genital	1	0
	Sexual function and fertility disorders	Spermatogenesis and semen disorders	Haemospermia	1	0
	Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular pain	1	0
	Total			17	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchial conditions NEC	Bronchiectasis	1	0
		Bronchospasm and obstruction	Asthma	4	0
			Bronchospasm	6	0
			Wheezing	7	0
	Lower respiratory tract disorders (excl obstruction and infection)	Parenchymal lung disorders NEC	Interstitial lung disease	1	0
			Lung consolidation	1	0
		Pulmonary oedemas	Acute respiratory distress syndrome	1	0
	Pleural disorders	Pneumothorax and pleural effusions NEC	Pleural effusion	1	0
	Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	2	0
			Apnoeic attack	1	0
			Dyspnoea	37	0
			Grunting	1	0
			Hyperventilation	6	0
			Hypoventilation	1	0
			Respiration abnormal	1	0
			Respiratory arrest	3	0
			Respiratory distress	1	0
			Sleep apnoea syndrome	2	0
			Tachypnoea	2	0
		Conditions associated with abnormal gas exchange	Hypoxia	1	0
		Coughing and associated symptoms	Cough	17	0
			Haemoptysis	1	0
		Respiratory failures (excl neonatal)	Acute respiratory failure	2	0
	Respiratory tract signs and symptoms	Upper respiratory tract signs and symptoms	Choking	2	0
			Dysphonia	1	0
			Oropharyngeal discomfort	1	0
			Oropharyngeal pain	13	0
			Rhinorrhoea	3	0
			Throat tightness	5	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGHT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Laryngeal oedema	1	0
			Stridor	3	0
		Nasal congestion and inflammations	Nasal congestion	2	0
		Nasal disorders NEC	Epistaxis	4	0
		Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	1	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal swelling	1	0
	Total			138	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	9	0
		Urticarias	Urticaria	107	0
			Urticaria papular	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	4	0
			Dermatitis bullous	1	0
			Erythema multiforme	10	0
			Pemphigus	1	0
			Stevens-Johnson syndrome	2	0
		Dermal and epidermal conditions NEC	Dry skin	3	0
			Pain of skin	1	0
			Skin discolouration	5	0
			Skin induration	1	0
			Skin plaque	1	0
			Skin reaction	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Dermatitis and eczema	Dermatitis	1	0
			Dermatitis allergic	9	0
			Eczema	4	0
			Skin irritation	1	0
		Dermatitis ascribed to specific agent	Drug reaction with eosinophilia and systemic symptoms	1	0
		Erythemas	Erythema	29	0
		Exfoliative conditions	Exfoliative rash	1	0
			Skin exfoliation	1	0
		Papulosquamous conditions	Lichen planus	1	0
		Photosensitivity and photodermatitis conditions	Photosensitivity reaction	1	0
		Pruritus NEC	Pruritus	31	0
		Psoriatic conditions	Psoriasis	1	0
		Rashes, eruptions and exanthems NEC	Rash	62	0
			Rash erythematous	25	0
			Rash macular	18	0
			Rash maculo-papular	16	0
			Rash morbilliform	3	0
			Rash papular	8	0
			Rash pruritic	18	0
			Rash vesicular	2	0
	Pigmentation disorders	Pigmentation changes NEC	Pigmentation disorder	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Skin and subcutaneous tissue disorders NEC	Panniculitides	Erythema nodosum	5	0
			Panniculitis	1	0
	Skin appendage conditions	Alopecias	Alopecia	1	0
		Apocrine and eccrine gland disorders	Cold sweat	11	0
			Hyperhidrosis	56	0
			Night sweats	4	0
			Sweat discolouration	1	0
	Skin vascular abnormalities	Purpura and related conditions	Ecchymosis	1	0
			Petechiae	4	0
			Purpura	8	0
		Skin vasculitides	Hypersensitivity vasculitis	1	0
			Vasculitic rash	2	0
		Skin vasomotor conditions	Livedo reticularis	1	0
	Total			477	0
Social circumstances	Lifestyle issues	Disability issues	Impaired driving ability	1	0
	Total			1	0
Surgical and medical procedures	Obstetric and gynaecological therapeutic procedures	Induced abortions	Abortion induced	2	0
		Obstetric therapeutic procedures	Caesarean section	1	0
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Interchange of vaccine products	1	0
	Total			4	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Non-site specific necrosis and vascular insufficiency NEC	Vasospasm	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	4	0
			Peripheral ischaemia	1	0
			Poor peripheral circulation	1	0
			Raynaud's phenomenon	1	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	24	0
		Vascular hypotensive disorders	Hypotension	28	0
			Orthostatic hypotension	1	0
	Embolism and thrombosis	Peripheral embolism and thrombosis	Axillary vein thrombosis	1	0
			Thrombophlebitis	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	20	0
			Flushing	14	0
			Hot flush	6	0
		Site specific vascular disorders NEC	Pallor	47	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	6	0
	Vascular infections and inflammations	Arterial infections and inflammations	Arteritis	1	0
		Vasculitides NEC	Vasculitis	1	0
	Total			161	0
Total				4,807	7

Number of ADR Reports

1,856