

Tetanus Diphtheria and Polio (Td/IPV) Vaccine Analysis Print.

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

Report run: 06/05/2025

Earliest reaction date: 01/05/1983

Reaction MedDRA SOC Name	Reaction MedDRA HLGST 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	1	0
		Marrow depression and hypoplastic anaemias	Aplastic anaemia	2	1
			Pancytopenia	1	0
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Haemorrhagic disorder	1	0
		Coagulopathies	Coagulopathy	2	0
			Disseminated intravascular coagulation	1	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	2	0
			Thrombocytopenia	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	1	0
			Lymphadenitis	2	0
			Lymphadenopathy	40	0
	White blood cell disorders	Leukocytoses NEC	Leukocytosis	1	0
		Neutropenias	Neutropenia	4	0
	Total			59	1
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Arrhythmia	2	0
			Bradycardia	4	0
			Tachycardia	23	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG T Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Supraventricular arrhythmias	Atrial fibrillation	1	0
			Supraventricular tachycardia	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	7	0
	Coronary artery disorders	Coronary artery disorders NEC	Arteriosclerosis coronary artery	1	0
	Heart failures	Left ventricular failures	Left ventricular failure	1	1
	Myocardial disorders	Myocardial disorders NEC	Cardiomegaly	1	0
			Left ventricular dysfunction	1	0
	Pericardial disorders	Pericardial disorders NEC	Pericardial effusion	1	0
	Total			43	1
Congenital, familial and genetic disorders	Chromosomal abnormalities, gene alterations and gene variants	Autosomal chromosomal abnormalities	Trisomy 21	1	0
	Congenital and hereditary disorders NEC	Congenital disorders NEC	Congenital cyst	1	0
	Gastrointestinal tract disorders congenital	Oral cavity disorders congenital NEC	Tethered oral tissue	1	0
	Musculoskeletal and connective tissue disorders congenital	Musculoskeletal and connective tissue disorders of limbs congenital	Syndactyly	1	0
		Musculoskeletal and connective tissue disorders of skull congenital	Plagiocephaly	1	0
	Neurological disorders congenital	Neurological disorders congenital NEC	Tourette's disorder	1	0
		Peripheral nervous system disorders congenital NEC	Paroxysmal extreme pain disorder	1	0
	Skin and subcutaneous tissue disorders congenital	Skin and subcutaneous tissue disorders congenital NEC	Congenital skin dimples	1	0
	Total			8	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear discomfort	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Ear pain	4	0
			Ear swelling	1	0
	Hearing disorders	Hearing losses	Deafness	3	0
			Deafness neurosensory	1	0
			Deafness unilateral	2	0
			Hypoacusis	7	0
		Hyperacusis	Hyperacusis	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Vestibular disorder	1	0
		Inner ear signs and symptoms	Tinnitus	8	0
			Vertigo	14	0
			Vertigo positional	2	0
	Middle ear disorders (excl congenital)	Tympanic membrane disorders (excl infections)	Tympanic membrane perforation	1	0
	Total			48	0
Endocrine disorders	Adrenal gland disorders	Adrenal gland disorders NEC	Adrenal disorder	1	0
	Total			1	0
Eye disorders	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	1	0
		Ocular disorders NEC	Eye pain	15	0
			Eye swelling	23	0
			Periorbital swelling	1	0
	Ocular infections, irritations and inflammations	Conjunctival infections, irritations and inflammations	Conjunctivitis allergic	1	0
		Lid, lash and lacrimal infections, irritations and inflammations	Erythema of eyelid	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Eyelid oedema	2	0
			Swelling of eyelid	7	0
		Ocular infections, inflammations and associated manifestations	Eye irritation	5	0
			Eye pruritus	5	0
			Ocular hyperaemia	8	0
		Orbital infections, inflammations and irritations	Parophthalmia	1	0
		Retinal, choroid and vitreous infections and inflammations	Retinal vasculitis	1	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Blepharospasm	1	0
		Ocular nerve and muscle disorders	Binocular eye movement disorder	1	0
			Eye movement disorder	31	0
			Gaze palsy	2	0
			Strabismus	1	0
		Pupil disorders	Mydriasis	11	0
			Pupil fixed	2	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	3	0
			Photophobia	31	0
	Vision disorders	Visual colour distortions	Xanthopsia	1	0
		Visual disorders NEC	Diplopia	4	0
			Photopsia	3	0
			Vision blurred	36	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Visual impairment and blindness (excl colour blindness)	Amaurosis fugax	1	0
			Blindness	3	0
			Blindness transient	3	0
			Visual impairment	15	0
	Total			220	0
Gastrointestinal disorders	Abdominal hernias and other abdominal wall conditions	Umbilical hernias	Umbilical hernia	2	0
	Dental and gingival conditions	Dental pain and sensation disorders	Hyperaesthesia teeth	1	0
		Dental surface disorders	Tooth discolouration	1	0
		Gingival disorders, signs and symptoms NEC	Gingival pain	1	0
	Exocrine pancreas conditions	Acute and chronic pancreatitis	Pancreatitis	1	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	2	0
	Gastrointestinal haemorrhages NEC	Intestinal haemorrhages	Rectal haemorrhage	1	0
		Non-site specific gastrointestinal haemorrhages	Haematemesis	3	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis ulcerative	2	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	82	0
			Diarrhoea haemorrhagic	1	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	3	0
			Gastrooesophageal reflux disease	4	0
			Impaired gastric emptying	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Gastrointestinal spastic and hypermotility disorders	Frequent bowel movements	2	0
			Irritable bowel syndrome	2	0
	Gastrointestinal signs and symptoms	Faecal abnormalities NEC	Faeces pale	1	0
		Flatulence, bloating and distension	Abdominal distension	2	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	40	0
			Abdominal pain lower	2	0
			Abdominal pain upper	53	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	13	0
			Anal incontinence	1	0
			Dysphagia	14	0
		Nausea and vomiting symptoms	Nausea	375	0
			Retching	2	0
			Vomiting	241	0
			Vomiting projectile	2	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Chapped lips	1	0
			Oral disorder	1	0
		Oral soft tissue signs and symptoms	Hypoaesthesia oral	4	0
			Oral discomfort	1	0
			Oral pain	3	0
			Oral pruritus	2	0
			Paraesthesia oral	16	0
		Oral soft tissue swelling and oedema	Lip swelling	27	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal	
			Mouth swelling	3	0	
		Stomatitis and ulceration	Mouth ulceration	1	0	
			Stomatitis	1	0	
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	2	0	
			Salivary hypersecretion	1	0	
		Salivary gland enlargements	Parotid gland enlargement	1	0	
	Tongue conditions	Tongue disorders	Glossitis	1	0	
			Tongue disorder	1	0	
		Tongue signs and symptoms	Swollen tongue	11	0	
			Tongue coated	1	0	
			Tongue discolouration	1	0	
			Tongue movement disturbance	1	0	
	Total			935	0	
	General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site bruise	1	0
			Application site reactions	Application site erythema	1	0
Infusion site reactions			Infusion site discomfort	1	0	
Injection site reactions			Injected limb mobility decreased	3	0	
			Injection site bruising	3	0	
			Injection site coldness	1	0	
			Injection site discolouration	2	0	
			Injection site discomfort	1	0	
			Injection site erythema	34	0	

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Injection site haemorrhage	3	0
			Injection site hypersensitivity	1	0
			Injection site induration	4	0
			Injection site inflammation	8	0
			Injection site irritation	1	0
			Injection site mass	7	0
			Injection site movement impairment	3	0
			Injection site necrosis	1	0
			Injection site nodule	1	0
			Injection site pain	30	0
			Injection site paraesthesia	1	0
			Injection site pruritus	8	0
			Injection site rash	12	0
			Injection site reaction	18	0
			Injection site swelling	24	0
			Injection site urticaria	1	0
			Injection site vesicles	1	0
			Injection site warmth	5	0
		Vaccination site reactions	Extensive swelling of vaccinated limb	2	0
			Shoulder injury related to vaccine administration	1	0
			Vaccination site bruising	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Vaccination site discomfort	1	0
			Vaccination site eczema	1	0
			Vaccination site erythema	24	0
			Vaccination site induration	2	0
			Vaccination site inflammation	5	0
			Vaccination site joint pain	2	0
			Vaccination site mass	2	0
			Vaccination site movement impairment	3	0
			Vaccination site nodule	1	0
			Vaccination site pain	43	0
			Vaccination site papule	1	0
			Vaccination site paraesthesia	1	0
			Vaccination site pruritus	2	0
			Vaccination site rash	3	0
			Vaccination site reaction	4	0
			Vaccination site scab	1	0
			Vaccination site swelling	28	0
			Vaccination site vesicles	1	0
			Vaccination site warmth	6	0
	Body temperature conditions	Febrile disorders	Hyperpyrexia	2	0
			Pyrexia	528	0
	General system disorders NEC	Asthenic conditions	Asthenia	54	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Chronic fatigue syndrome	3	0
			Fatigue	160	0
			Malaise	374	0
		Feelings and sensations NEC	Chills	100	0
			Feeling abnormal	21	0
			Feeling cold	24	0
			Feeling hot	85	0
			Feeling of body temperature change	21	0
			Sensation of foreign body	2	0
			Thirst	3	0
			Thirst decreased	1	0
		Gait disturbances	Gait disturbance	9	0
			Gait inability	5	0
		General signs and symptoms NEC	Condition aggravated	8	0
			Crepitations	2	0
			Crying	7	0
			Developmental delay	1	0
			Effusion	1	0
			Exercise tolerance decreased	1	0
			Illness	49	0
			Induration	3	0
			Influenza like illness	92	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Irritability postvaccinal	1	0
			Local reaction	24	0
			Multiple organ dysfunction syndrome	1	0
			Peripheral swelling	79	0
			Screaming	1	0
			Swelling	44	0
			Swelling face	27	0
		Inflammations	Inflammation	17	0
			Systemic inflammatory response syndrome	2	0
		Oedema NEC	Face oedema	5	0
		Pain and discomfort NEC	Axillary pain	10	0
			Chest discomfort	21	0
			Chest pain	29	0
			Discomfort	9	0
			Facial pain	1	0
			Pain	116	0
			Tenderness	13	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse drug reaction	4	0
	Tissue disorders NEC	Mass conditions NEC	Cyst	1	0
			Mass	4	0
	Total			2,278	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Hepatobiliary disorders	Bile duct disorders	Bile duct infections and inflammations	Cholangitis sclerosing	1	0
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	11	0
		Hepatic enzymes and function abnormalities	Hepatic function abnormal	2	0
			Hypertransaminasaemia	1	0
		Hepatic failure and associated disorders	Acute hepatic failure	1	0
		Hepatobiliary signs and symptoms	Hepatomegaly	1	0
		Hepatocellular damage and hepatitis NEC	Autoimmune hepatitis	1	0
			Hepatitis acute	2	0
			Liver injury	1	0
	Total			21	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergy to animal	1	0
			Hypersensitivity	32	0
			Mite allergy	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergic reaction to excipient	1	0
			Allergy to vaccine	2	0
			Food allergy	1	0
			Reaction to excipient	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	58	0
			Anaphylactic shock	2	0
			Anaphylactoid reaction	2	0
		Atopic disorders	Seasonal allergy	1	0
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Immune disorders NEC	Immune and associated conditions NEC	Bacille Calmette-Guerin scar reactivation	1	0
			Haemophagocytic lymphohistiocytosis	1	1
			Immune system disorder	1	0
			Immune-mediated adverse reaction	1	0
			Multisystem inflammatory syndrome in children	1	0
	Total			109	1
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Arthritis bacterial	1	0
			Cellulitis	10	0
			Injection site cellulitis	3	0
			Meningitis bacterial	1	0
			Tonsillitis bacterial	1	0
		Bordetella infections	Pertussis	1	0
		Corynebacteria infections	Corynebacterium infection	2	0
			Diphtheria	1	0
		Staphylococcal infections	Staphylococcal abscess	1	0
		Streptococcal infections	Pneumococcal sepsis	1	1
			Streptococcal infection	1	0
	Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Appendicitis perforated	1	0
		Central nervous system and spinal infections	Encephalitis	1	0
			Meningitis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Meningitis aseptic	1	0
			Myelitis	1	0
		Ear infections	Ear infection	1	0
			Labyrinthitis	1	0
		Eye and eyelid infections	Conjunctivitis	1	0
		Infections NEC	Infection	4	0
			Injection site abscess	1	0
			Respiratory tract infection	1	0
			Vestibulitis	1	0
		Lower respiratory tract and lung infections	Bronchitis	1	0
			Lower respiratory tract infection	4	0
		Muscle and soft tissue infections	Soft tissue infection	1	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Neutropenic sepsis	1	0
			Sepsis	4	0
		Skin structures and soft tissue infections	Skin infection	3	0
		Upper respiratory tract infections	Nasopharyngitis	21	0
			Pharyngitis	3	0
			Rhinitis	2	0
			Sinusitis	1	0
			Tonsillitis	3	0
		Urinary tract infections	Urinary tract infection	1	0
		Vascular infections	Lymphangitis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Viral infectious disorders	Coronavirus infections	COVID-19	1	0
		Epstein-Barr viral infections	Infectious mononucleosis	3	0
		Flaviviral infections	Yellow fever vaccine-associated viscerotropic disease	1	0
		Hepatitis virus infections	Hepatitis A	1	0
		Herpes viral infections	Herpes simplex	1	0
			Herpes zoster	2	0
		Influenza viral infections	Influenza	8	0
		Mumps viral infections	Mumps	1	0
		Viral infections NEC	Encephalitis viral	1	0
			Meningitis viral	1	0
			Viral diarrhoea	1	0
			Viral infection	3	0
			Viral pericarditis	1	0
	Total			109	1
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	10	0
			Foetal exposure during pregnancy	8	0
			Foetal exposure timing unspecified	1	0
			Maternal exposure before pregnancy	2	0
			Maternal exposure during pregnancy	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Injuries NEC	Poisoning and toxicity	Toxicity to various agents	1	0
		Muscle, tendon and ligament injuries	Epicondylitis	1	0
			Muscle injury	1	0
		Nerve injuries NEC	Nerve injury	1	0
		Non-site specific injuries NEC	Fall	5	0
			Traumatic haematoma	1	0
		Reproductive system and breast injuries	Perineal injury	1	0
		Site specific injuries NEC	Head injury	1	0
		Skin injuries NEC	Contusion	10	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	2	0
			Vaccination error	1	0
			Wrong technique in product usage process	1	0
		Product administration errors and issues	Expired product administered	3	0
			Extra dose administered	4	0
			Inappropriate schedule of product administration	1	0
			Product administered at inappropriate site	1	0
			Product administered to patient of inappropriate age	2	0
			Product administration error	1	0
			Wrong product administered	8	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
	Off label uses and intentional product misuses/use issues	Off label uses	Off label use	1	0
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	2	0
	Procedural related injuries and complications NEC	Gastrointestinal and hepatobiliary procedural complications	Procedural nausea	1	0
		Non-site specific procedural complications	Shunt malfunction	1	0
		Vaccination related complications	Immunisation reaction	4	0
	Total			80	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	ECG investigations	Electrocardiogram abnormal	1	0
		Heart rate and pulse investigations	Heart rate decreased	3	0
			Heart rate increased	12	0
			Heart rate irregular	3	0
			Pulse abnormal	18	0
			Pulse absent	1	0
		Vascular tests NEC (incl blood pressure)	Blood pressure abnormal	1	0
			Blood pressure decreased	5	0
			Blood pressure diastolic increased	1	0
			Blood pressure increased	6	0
	Cytogenetic investigations and genetic analyses	Cell marker analyses	Carbohydrate antigen 19-9 increased	1	0
	Foetal and neonatal investigations	Foetal and neonatal diagnostic procedures	Foetal heart rate abnormal	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	Foetal monitoring abnormal	1	0
			International normalised ratio increased	1	0
			Red blood cell sedimentation rate increased	1	0
			Platelet count increased	1	0
			Platelet morphology abnormal	1	0
			Lymphocyte count increased	1	0
			Lymphocyte morphology abnormal	2	0
			Neutrophil count abnormal	2	0
			Neutrophil toxic granulation present	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	4	0
			Aspartate aminotransferase increased	1	0
			Blood bilirubin increased	3	0
			Liver function test abnormal	4	0
			Liver function test increased	1	0
			Transaminases increased	1	0
	Investigations, imaging and histopathology procedures NEC	Investigations NEC	Quality of life decreased	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	5	0
			Blood glucose increased	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Vitamin analyses	Vitamin D decreased	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature	2	0
			Body temperature abnormal	1	0
			Body temperature decreased	1	0
			Body temperature fluctuation	1	0
			Body temperature increased	80	0
			General physical condition abnormal	1	0
			Respiratory rate increased	5	0
			Weight decreased	3	0
			Weight increased	1	0
	Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	1	0
		Protein analyses NEC	C-reactive protein increased	3	0
	Renal and urinary tract investigations and urinalyses	Urinalysis NEC	Blood urine present	3	0
	Respiratory and pulmonary investigations (excl blood gases)	Respiratory and pulmonary function diagnostic procedures	Vital capacity decreased	1	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood iron decreased	1	0
	Total			194	0
Metabolism and nutrition disorders	Acid-base disorders	Mixed acid-base disorders	Acidosis	1	0
	Appetite and general nutritional disorders	Appetite disorders	Appetite disorder	1	0
			Decreased appetite	61	0
			Hypophagia	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		General nutritional disorders NEC	Abnormal loss of weight	2	0
			Feeding disorder	2	0
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	1	0
			Food intolerance	1	0
			Milk soy protein intolerance	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Hyperglycaemic conditions NEC	Glucose tolerance impaired	1	0
			Insulin resistance	2	0
		Hypoglycaemic conditions NEC	Hypoglycaemia	1	0
	Total			75	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone disorders NEC	Jaw disorder	1	0
		Bone related signs and symptoms	Bone pain	1	0
			Pain in jaw	2	0
			Spinal pain	2	0
		Metabolic bone disorders	Osteoporosis	1	0
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Connective tissue disorder	1	0
			Morphoea	1	0
			Myofascitis	1	0
			Polymyalgia rheumatica	1	0
	Joint disorders	Arthropathies NEC	Arthritis	3	0
			Arthropathy	2	0
		Joint related disorders NEC	Periarthritis	2	0
		Joint related signs and symptoms	Arthralgia	92	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Joint effusion	1	0
			Joint stiffness	7	0
			Joint swelling	6	0
		Rheumatoid arthropathies	Rheumatoid arthritis	3	0
		Spondyloarthropathies	Ankylosing spondylitis	1	0
	Muscle disorders	Muscle infections and inflammations	Myositis	1	0
		Muscle pains	Myalgia	104	0
		Muscle related signs and symptoms NEC	Muscle atrophy	2	0
			Muscle fatigue	4	0
			Muscle spasms	17	0
			Muscle swelling	3	0
			Muscle twitching	18	0
		Muscle tone abnormalities	Muscle rigidity	15	0
			Trismus	5	0
		Muscle weakness conditions	Muscular weakness	32	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Growth retardation	1	0
			Limb mass	1	0
			Mastication disorder	1	0
			Mobility decreased	3	0
			Musculoskeletal stiffness	47	0
			Posture abnormal	2	0
			Weight bearing difficulty	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Musculoskeletal and connective tissue infections and inflammations NEC	Dactylitis	1	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	64	0
			Limb discomfort	21	0
			Musculoskeletal chest pain	1	0
			Musculoskeletal discomfort	1	0
			Musculoskeletal pain	3	0
			Neck pain	33	0
			Pain in extremity	200	0
			Rheumatic disorder	1	0
		Soft tissue disorders NEC	Axillary mass	4	0
			Groin pain	1	0
			Neck mass	1	0
	Synovial and bursal disorders	Bursal disorders	Bursitis	2	0
	Tendon, ligament and cartilage disorders	Tendon disorders	Tendonitis	1	0
			Tenosynovitis	1	0
	Total			720	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal neoplasms malignant and unspecified	Pancreatic neoplasms malignant (excl islet cell and carcinoid)	Adenocarcinoma pancreas	1	0
	Haematopoietic neoplasms (excl leukaemias and lymphomas)	Histiocytoses	Histiocytosis	1	0
	Reproductive neoplasms female benign	Reproductive neoplasms female benign NEC	Benign hydatidiform mole	1	0
	Total			3	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	Myelitis (incl infective)	Myelitis transverse	1	0
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral haemorrhage	1	1
		Cerebrovascular venous and sinus thrombosis	Cerebral venous sinus thrombosis	1	0
		Transient cerebrovascular events	Transient ischaemic attack	1	0
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	4	0
			Facial paralysis	2	0
			Facial paresis	1	0
			Facial spasm	1	0
		Trigeminal disorders	Trigeminal neuralgia	2	0
	Demyelinating disorders	Demyelinating disorders NEC	Acute disseminated encephalomyelitis	4	0
		Multiple sclerosis acute and progressive	Multiple sclerosis	1	0
	Encephalopathies	Encephalopathies NEC	Encephalopathy	1	0
	Headaches	Headaches NEC	Cluster headache	1	0
			Headache	558	0
			Primary stabbing headache	1	0
			Tension headache	3	0
		Migraine headaches	Migraine	12	0
			Migraine with aura	1	0
	Mental impairment disorders	Intellectual disabilities	Intellectual disability	1	0
		Memory loss (excl dementia)	Amnesia	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Mental impairment (excl dementia and memory loss)	Memory impairment	2	0
			Cognitive disorder	3	0
			Disturbance in attention	9	0
			Judgement impaired	1	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	34	0
			Hypokinesia	7	0
			Movement disorder	1	0
			Psychomotor hyperactivity	2	0
		Dystonias	Opisthotonus	2	0
		Paralysis and paresis (excl cranial nerve)	Diplegia	2	0
			Hemiparesis	2	0
			Monoparesis	1	0
			Monoplegia	1	0
			Paralysis	3	0
			Quadriparesis	1	0
		Tremor (excl congenital)	Intention tremor	1	0
			Tremor	72	0
	Neurological disorders NEC	Coma states	Coma	1	0
		Coordination and balance disturbances	Ataxia	3	0
			Balance disorder	7	0
			Cerebellar ataxia	1	0
			Cerebellar syndrome	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Coordination abnormal	2	0
			Developmental coordination disorder	1	0
			Dysstasia	2	0
		Cortical dysfunction NEC	Aphasia	2	0
			Sensory processing disorder	1	0
		Disturbances in consciousness NEC	Altered state of consciousness	1	0
			Consciousness fluctuating	1	0
			Depressed level of consciousness	3	0
			Lethargy	69	0
			Loss of consciousness	40	0
			Somnolence	55	0
			Syncope	243	0
		Nervous system disorders NEC	Brain stem syndrome	1	0
		Neurological signs and symptoms NEC	Brain fog	1	0
			Dizziness	459	0
			Dizziness postural	4	0
			Drooling	1	0
			Head discomfort	6	0
			Hyporesponsive to stimuli	1	0
			Myoclonus	4	0
			Neurological symptom	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Presyncope	39	0
			Unresponsive to stimuli	21	0
		Paraesthesias and dysaesthesias	Burning sensation	5	0
			Dysaesthesia	1	0
			Formication	1	0
			Hyperaesthesia	2	0
			Hypoaesthesia	57	0
			Paraesthesia	80	0
		Sensory abnormalities NEC	Ageusia	1	0
			Dysgeusia	3	0
			Electric shock sensation	1	0
			Neuralgia	3	0
			Sensory disturbance	3	0
			Sensory loss	6	0
			Taste disorder	1	0
		Speech and language abnormalities	Dysarthria	10	0
			Incoherent	1	0
			Speech disorder	4	0
	Neurological disorders of the eye	Neurologic visual problems NEC	Tunnel vision	2	0
	Neuromuscular disorders	Muscle tone abnormal	Hypertonia	1	0
			Hypotonia	6	0
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Muscle spasticity	1	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	5	0
		Chronic polyneuropathies	Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
			Demyelinating polyneuropathy	1	0
		Peripheral neuropathies NEC	Neuropathy peripheral	3	0
			Peripheral sensory neuropathy	1	0
			Polyneuropathy	1	0
	Seizures (incl subtypes)	Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	3	0
		Seizures and seizure disorders NEC	Epilepsy	5	0
			Febrile convulsion	3	0
			Myoclonic epilepsy	1	0
			Seizure	39	0
			Seizure like phenomena	4	0
			Tonic clonic movements	3	0
			Tonic convulsion	2	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	9	0
	Spinal cord and nerve root disorders	Spinal cord and nerve root disorders NEC	Radiculitis brachial	4	0
	Total			1,991	1
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortion related conditions and complications	Anembryonic gestation	1	0
		Abortions spontaneous	Abortion spontaneous	13	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Foetal complications	Foetal complications NEC	Foetal cardiac disorder	1	0
			Foetal distress syndrome	4	0
			Foetal hypokinesia	1	0
		Foetal growth complications	Foetal growth restriction	1	0
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Prolonged labour	1	0
		Maternal complications of delivery NEC	Complication of delivery	1	0
	Maternal complications of pregnancy	Haemorrhagic complications of pregnancy	Haemorrhage in pregnancy	1	0
			Complication of pregnancy	1	0
		Maternal complications of pregnancy NEC	Ectopic pregnancy	1	0
	Neonatal and perinatal conditions	Gestational age and weight conditions	Premature baby	1	0
		Neonatal hepatobiliary disorders	Jaundice neonatal	1	0
	Placental, amniotic and cavity disorders (excl haemorrhages)	Amniotic fluid and cavity disorders of pregnancy NEC	Meconium in amniotic fluid	1	0
	Pregnancy, labour, delivery and postpartum conditions	Normal newborn status	Normal newborn	1	0
	Total			30	0
Psychiatric disorders	Adjustment disorders (incl subtypes)	Adjustment disorders	Adjustment disorder	7	0
	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	7	0
			Anxiety	16	0
			Nervousness	3	0
			Stress	1	0
		Fear symptoms and phobic disorders (incl social phobia)	Fear	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Panic attacks and disorders	Panic attack	2	0
			Panic reaction	3	0
	Changes in physical activity	Increased physical activity levels	Restlessness	1	0
		Stereotypies and automatisms	Bruxism	2	0
		Tic disorders	Tic	1	0
	Cognitive and attention disorders and disturbances	Cognitive and attention disorders and disturbances NEC	Mental fatigue	1	0
		Learning disorders	Learning disability	1	0
	Communication disorders and disturbances	Communications disorders	Communication disorder	1	0
		Speech articulation and rhythm disturbances	Lack of spontaneous speech	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	18	0
			Disorientation	19	0
		Deliria	Delirium	7	0
	Depressed mood disorders and disturbances	Depressive disorders	Depression	1	0
		Mood alterations with depressive symptoms	Depressed mood	2	0
			Tearfulness	2	0
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	1	0
	Dissociative disorders	Dissociative states	Dissociation	1	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	11	0
			Hallucination, visual	1	0
	Eating disorders and disturbances	Eating disorders NEC	Eating disorder	1	0
	Mood disorders and disturbances NEC	Affect alterations NEC	Affect lability	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Emotional and mood disturbances NEC	Emotional disorder	4	0
			Emotional distress	3	0
			Irritability	3	0
			Mood altered	1	0
		Mood disorders NEC	Affective disorder	1	0
			Listless	3	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	3	0
			Indifference	1	0
			Paranoia	1	0
		Personality disorders with dramatic behaviour (Cluster B)	Borderline personality disorder	1	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	3	0
	Psychiatric disorders NEC	Mental disorders NEC	Mental disorder	2	0
		Psychiatric elimination disorders	Enuresis	2	0
	Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Acute psychosis	1	0
			Psychotic disorder	2	0
		Schizophrenia NEC	Schizophrenia	2	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	13	0
			Middle insomnia	1	0
		Dyssomnias	Poor quality sleep	2	0
		Parasomnias	Nightmare	1	0
		Sleep disorders NEC	Sleep disorder	12	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Somatic symptom and related disorders	Somatic symptom disorders	Conversion disorder	1	0
			Somatic symptom disorder	1	0
	Total			177	0
Renal and urinary disorders	Nephropathies	Glomerulonephritis and nephrotic syndrome	Glomerulonephritis acute	1	0
			Goodpasture's syndrome	1	0
		Nephritis NEC	Nephritis	1	0
	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	2	0
			Renal failure	1	0
		Renal failure complications	Azotaemia	1	0
		Renal obstructive disorders	Hydronephrosis	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Dysuria	2	0
			Incontinence	5	0
			Mixed incontinence	1	0
			Pollakiuria	1	0
			Urinary incontinence	5	0
		Urinary abnormalities	Chromaturia	4	0
			Haematuria	1	0
	Total			27	0
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms	Breast tenderness	1	0
	Menstrual cycle and uterine bleeding disorders	Menstruation and uterine bleeding NEC	Menstrual disorder	2	0
		Menstruation with decreased bleeding	Amenorrhoea	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG T Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Penile and scrotal disorders (excl infections and inflammations)	Penile disorders NEC (excl erection and ejaculation)	Penis disorder	2	0
		Scrotal disorders NEC	Scrotal pain	1	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Pelvic pain	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
			Testicular swelling	3	0
	Total			15	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchial conditions NEC	Bronchial secretion retention	1	0
			Fibrinous bronchitis	1	0
		Bronchospasm and obstruction	Asthma	8	0
			Bronchospasm	1	0
			Obstructive airways disorder	1	0
			Wheezing	11	0
	Lower respiratory tract disorders (excl obstruction and infection)	Parenchymal lung disorders NEC	Lung consolidation	1	0
	Pleural disorders	Pleural infections and inflammations	Pleurisy	1	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	60	0
			Grunting	2	0
			Hyperventilation	8	0
			Hypopnoea	3	0
			Respiration abnormal	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Respiratory arrest	2	0
			Tachypnoea	1	0
		Conditions associated with abnormal gas exchange	Hypoxia	1	0
		Coughing and associated symptoms	Cough	19	0
			Haemoptysis	1	0
	Respiratory tract signs and symptoms	Respiratory signs and symptoms NEC	Painful respiration	2	0
		Upper respiratory tract signs and symptoms	Aphonia	2	0
			Choking	1	0
			Dry throat	2	0
			Dysphonia	4	0
			Oropharyngeal discomfort	2	0
			Oropharyngeal pain	63	0
			Rhinorrhoea	5	0
			Throat irritation	8	0
			Throat tightness	13	0
	Upper respiratory tract disorders (excl infections)	Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	Laryngeal dyskinesia	1	0
			Vocal fold immobility	1	0
		Laryngeal spasm, oedema and obstruction	Stridor	1	0
		Nasal congestion and inflammations	Nasal congestion	6	0
		Nasal disorders NEC	Epistaxis	7	0
		Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal erythema	1	0
			Pharyngeal hypoaesthesia	2	0
			Pharyngeal inflammation	1	0
			Pharyngeal paraesthesia	1	0
			Pharyngeal swelling	11	0
			Tonsillar erythema	1	0
	Total			259	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria disorders	Angioedemas	Angioedema	7	0
		Urticarias	Urticaria	62	0
			Urticaria chronic	2	0
	Cornification and dystrophic skin disorders	Skin hyperplasias and hypertrophies	Skin hypertrophy	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	1	0
			Erythema multiforme	3	0
		Dermal and epidermal conditions NEC	Dry skin	5	0
			Macule	1	0
			Pain of skin	3	0
			Papule	1	0
			Sensitive skin	7	0
			Skin burning sensation	1	0
			Skin discolouration	15	0
			Skin discomfort	1	0
			Skin induration	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Skin lesion	1	0
			Skin reaction	2	0
			Skin swelling	1	0
			Skin warm	16	0
		Dermatitis and eczema	Dermatitis	2	0
			Dermatitis allergic	6	0
			Eczema	4	0
			Skin irritation	2	0
		Erythemas	Erythema	99	0
		Exfoliative conditions	Exfoliative rash	1	0
			Skin exfoliation	2	0
		Papulosquamous conditions	Pityriasis rosea	3	0
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	3	0
		Pruritus NEC	Pruritus	58	0
		Rashes, eruptions and exanthems NEC	Rash	154	0
			Rash erythematous	10	0
			Rash macular	23	0
			Rash maculo-papular	2	0
			Rash papular	8	0
			Rash pruritic	12	0
			Rash rubelliform	1	0
	Pigmentation disorders	Hyperpigmentation disorders	Solar lentigo	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Pigmentation changes NEC	Pigmentation disorder	1	0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Subcutaneous emphysema	2	0
	Skin appendage conditions	Acnes	Acne	1	0
		Apocrine and eccrine gland disorders	Cold sweat	39	0
			Hyperhidrosis	51	0
			Night sweats	3	0
	Skin vascular abnormalities	Purpura and related conditions	Ecchymosis	1	0
			Henoch-Schonlein purpura	3	0
			Petechiae	3	0
			Purpura	3	0
		Skin vasculitides	Cutaneous vasculitis	1	0
		Skin vasomotor conditions	Livedo reticularis	6	0
	Total			637	0
Social circumstances	Lifestyle issues	Disability issues	Impaired work ability	2	0
			Loss of personal independence in daily activities	1	0
	Total			3	0
Surgical and medical procedures	Obstetric and gynaecological therapeutic procedures	Induced abortions	Abortion induced	4	0
		Obstetric therapeutic procedures	Caesarean section	3	0
			Vacuum extractor delivery	1	0
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Interchange of vaccine products	1	0
	Total			9	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	16	0
			Poor peripheral circulation	1	0
			Raynaud's phenomenon	2	0
	Decreased and nonspecific blood pressure disorders and shock	Blood pressure disorders NEC	Labile blood pressure	1	0
		Circulatory collapse and shock	Circulatory collapse	8	0
			Shock	3	0
		Vascular hypotensive disorders	Hypotension	25	0
			Orthostatic hypotension	1	0
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Thrombosis	1	0
		Peripheral embolism and thrombosis	Thrombophlebitis	2	0
	Lymphatic vessel disorders	Lymphoedemas	Lymphoedema	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	6	0
			Flushing	22	0
			Hot flush	4	0
		Site specific vascular disorders NEC	Pallor	113	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	3	0
	Vascular infections and inflammations	Arterial infections and inflammations	Giant cell arteritis	1	0
	Total			211	0
Total				8,262	5

Number of ADR Reports

2,505