

Revaxis Td/IPV Vaccine Analysis Print.  
All UK spontaneous suspected Adverse Drug Reaction (ADR)  
reports associated with the Revaxis Td/IPV vaccine up to and including  
14/05/2025.

Report run: 15/05/2025  
Earliest reaction date: 24/02/2004

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	1	0	
		Marrow depression and hypoplastic anaemias	Aplastic anaemia	2	1	
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Pancytopenia	1	0	
			Haemorrhagic disorder	1	0	
		Coagulopathies	Coagulopathy	2	0	
	Platelet disorders	Thrombocytopenias	Disseminated intravascular coagulation	1	0	
			Immune thrombocytopenia	2	0	
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Thrombocytopenia	1	0	
			Lymph node pain	1	0	
			Lymphadenitis	2	0	
White blood cell disorders	Leukocytoses NEC	Lymphadenopathy	37	0		
		Leukocytosis	1	0		
	Neutropenias	Neutropenia	4	0		
	Total			56	1	
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Arrhythmia	2	0	
			Bradycardia	4	0	
		Supraventricular arrhythmias	Tachycardia	22	0	
			Atrial fibrillation	1	0	
			Supraventricular tachycardia	1	0	
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	6	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			41	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
Ear pain				3	0	
Ear swelling				1	0	
Hearing disorders		Hearing losses	Deafness	3	0	
			Deafness neurosensory	1	0	
			Deafness unilateral	2	0	
			Hypacusis	7	0	
			Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Vestibular disorder	1
Inner ear signs and symptoms		Tinnitus			7	0
		Vertigo		14	0	
	Vertigo positional	2		0		
Middle ear disorders (excl congenital)	Tympanic membrane disorders (excl infections)	Tympanic membrane perforation	1	0		
	Total			45	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	14	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	
			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	29	0		
Vision disorders	Visual colour distortions	Xanthopsia	1	0		
	Visual disorders NEC	Diplopia	4	0		

			Photopsia	3	0	
			Vision blurred	34	0	
	Visual impairment and blindness (excl colour blindness)		Amaurosis fugax	1	0	
			Blindness	3	0	
			Blindness transient	3	0	
			Visual impairment	14	0	
	<b>Total</b>			<b>214</b>	<b>0</b>	
	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	79	0	
			Diarrhoea haemorrhagic	1	0	
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	2	0	
			Gastrooesophageal reflux disease	3	0	
			Impaired gastric emptying	1	0	
		Gastrointestinal spastic and hypermotility disorders	Frequent bowel movements	2	0	
			Irritable bowel syndrome	1	0	
Gastrointestinal signs and symptoms		Faecal abnormalities NEC	Faeces pale	1	0	
		Flatulence, bloating and distension	Abdominal distension	1	0	
			Abdominal pain	38	0	
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain lower	2	0	
			Abdominal pain upper	51	0	
			Abdominal discomfort	13	0	
		Gastrointestinal signs and symptoms NEC	Anal incontinence	1	0	
			Dysphagia	12	0	
			Nausea	368	0	
		Nausea and vomiting symptoms	Retching	2	0	
			Vomiting	236	0	
			Vomiting projectile	2	0	
			Oral soft tissue conditions	Oral soft tissue disorders NEC	Chapped lips	1
		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	
		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	
<b>Total</b>				<b>910</b>	<b>0</b>	
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	
			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	28	0	
			Injection site paraesthesia	1	0	
			Injection site pruritus	8	0	
			Injection site rash	12	0	
			Injection site reaction	17	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	
			Vaccination site discomfort	1	0	
			Vaccination site eczema	1	0	
			Vaccination site erythema	23	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	27	0	
			Vaccination site vesicles	1	0	
			Vaccination site warmth	6	0	
Body temperature conditions	Febrile disorders	Hyperpyrexia	2	0		
		Pyrexia	520	0		
General system disorders NEC	Asthenic conditions	Asthenia	50	0		
		Chronic fatigue syndrome	3	0		
		Fatigue	151	0		
		Malaise	366	0		
	Feelings and sensations NEC	Chills	97	0		
		Feeling abnormal	20	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		
		Illness	49	0		
		Induration	3	0		
		Influenza like illness	90	0		
		Irritability postvaccinal	1	0		
		Local reaction	25	0		
		Multiple organ dysfunction syndrome	1	0		
		Peripheral swelling	78	0		
		Screaming	1	0		
		Swelling	44	0		
		Swelling face	27	0		
		Inflammations	Inflammation	16	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		111	0		
	Tenderness		13	0		
	Adverse drug reaction		4	0		
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	4	0		
	Tissue disorders NEC	Mass conditions NEC	Cyst	1	0	
			Mass	4	0	
				2,231	0	
	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
					21	0
	Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergy to animal	1	0
				Hypersensitivity	31	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		

Infections and infestations			Anaphylactic shock	2	0
			Anaphylactoid reaction	2	0
	Atopic disorders		Seasonal allergy	1	0
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder	2	0
	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
	<b>Total</b>			<b>108</b>	<b>1</b>
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Arthritis bacterial	1	0
			Cellulitis	9	0
			Injection site cellulitis	2	0
			Meningitis bacterial	1	0
			Tonsillitis bacterial	1	0
			Pertussis	1	0
			Corynebacteria infections	1	0
			Staphylococcal infections	1	0
			Streptococcal infections	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
			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	3	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	2	0
		Urinary tract infections	Urinary tract infection	1	0
		Vascular infections	Lymphangitis	1	0
	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
	<b>Total</b>			<b>103</b>	<b>1</b>
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	9	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
			Toxicity to various agents	1	0
	Injuries NEC	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	8	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	3	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	
		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	
	<b>Total</b>			<b>76</b>	<b>0</b>	
	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	2	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	
			Foetal monitoring abnormal	1	0	
Haematology investigations (incl blood groups)		Coagulation and bleeding analyses	International normalised ratio increased	1	0	
		Haematological analyses NEC	Red blood cell sedimentation rate increased	1	0	
		Platelet analyses	Platelet count increased	1	0	
			Platelet morphology abnormal	1	0	
		White blood cell analyses	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	
		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	78	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	
<b>Total</b>				<b>191</b>	<b>0</b>	
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	59	0
				Hypophagia	1	0
			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	
	<b>Total</b>			<b>73</b>	<b>0</b>	
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	
			Arthralgia	89	0	
		Joint related signs and symptoms	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	101	0	
		Muscle related signs and symptoms NEC	Muscle atrophy	1	0	
			Muscle fatigue	4	0	
			Muscle spasms	17	0	
			Muscle swelling	3	0	
			Muscle twitching	17	0	
		Muscle tone abnormalities	Muscle rigidity	14	0	
			Trismus	5	0	
		Muscle weakness conditions	Muscular weakness	30	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	2	0	
			Musculoskeletal stiffness	44	0	
			Posture abnormal	2	0	
			Weight bearing difficulty	1	0	
			Dactylitis	1	0	
		Musculoskeletal and connective tissue infections and inflammations NEC				
			Musculoskeletal and connective tissue pain and discomfort	Back pain	63	0
				Limb discomfort	20	0
				Musculoskeletal chest pain	1	0
				Musculoskeletal discomfort	1	0
				Musculoskeletal pain	3	0
				Neck pain	32	0
				Pain in extremity	198	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	
	<b>Total</b>			<b>700</b>	<b>0</b>	
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	
	<b>Total</b>			<b>2</b>	<b>0</b>	
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			1	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	550	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	
			Memory impairment	1	0	
		Mental impairment (excl dementia and memory loss)	Cognitive disorder	2	0	
			Disturbance in attention	7	0	
	Judgement impaired		1	0		
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	33	0	
			Hypokinesia	7	0	

			Movement disorder	1	0
			Psychomotor hyperactivity	2	0
		Dystonias	Opisthotonus	1	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	
		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	38	0	
		Somnolence	54	0	
		Syncope	240	0	
	Nervous system disorders NEC	Brain stem syndrome	1	0	
	Neurological signs and symptoms NEC	Brain fog	1	0	
		Dizziness	452	0	
		Dizziness postural	4	0	
		Drooling	1	0	
		Head discomfort	5	0	
		Hyporesponsive to stimuli	1	0	
		Myoclonus	4	0	
		Neurological symptom	1	0	
		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		56	0	
	Paraesthesia		78	0	
	Sensory abnormalities NEC	Ageusia	1	0	
		Dysgeusia	3	0	
		Electric shock sensation	1	0	
		Neuralgia	2	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	3	0	
	Neurological disorders of the eye	Neurologic visual problems NEC	Tunnel vision	2	0
	Neuromuscular disorders	Muscle tone abnormal	Hypertonia	1	0
			Hypotonia	5	0
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	1	0
			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	3	0	
		Tonic clonic movements	3	0	
		Tonic convulsion	2	0	
Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	7	0	
Spinal cord and nerve root disorders	Spinal cord and nerve root disorders NEC	Radiculitis brachial	4	0	
Total			1,953	1	
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortion related conditions and complications	Anembryonic gestation	1	0
		Abortions spontaneous	Abortion spontaneous	12	0
	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	

Psychiatric disorders	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
		Maternal complications of pregnancy NEC	Complication of pregnancy	1	0
			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
	<b>Total</b>			<b>29</b>	<b>0</b>
	Adjustment disorders (incl subtypes)	Adjustment disorders	Adjustment disorder	7	0
	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	7	0
			Anxiety	15	0
			Nervousness	3	0
		Fear symptoms and phobic disorders (incl social phobia)	Fear	1	0
		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	Learning disorders	Learning disability	1	0
Renal and urinary disorders	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	17	0
			Disorientation	18	0
		Deliria	Delirium	7	0
	Depressed mood disorders and disturbances	Mood alterations with depressive symptoms	Depressed mood	1	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
		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	10	0
	Somatic symptom and related disorders	Somatic symptom disorders	Conversion disorder	1	0
			Somatic symptom disorder	1	0
	<b>Total</b>			<b>168</b>	<b>0</b>
	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	1	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	4	0
			Mixed incontinence	1	0
			Pollakiuria	1	0
			Urinary incontinence	5	0
		Urinary abnormalities	Chromaturia	4	0
			Haematuria	1	0
	<b>Total</b>			<b>25</b>	<b>0</b>
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms	Breast tenderness	1	0
	Menstrual cycle and uterine bleeding disorders	Menstruation with decreased bleeding	Amenorrhoea	1	0
	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	1	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
	<b>Total</b>			<b>12</b>	<b>0</b>
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	1	0
		Hyperventilation	8	0
		Hypopnoea	3	0
		Respiration abnormal	1	0
		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	61	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	4	0
	Nasal disorders NEC	Epistaxis	6	0
	Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	1	0
	Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal erythema	1	0
		Pharyngeal hypoaesthesia	2	0
		Pharyngeal paraesthesia	1	0
		Pharyngeal swelling	10	0
		Tonsillar erythema	1	0
<b>Total</b>			<b>251</b>	<b>0</b>
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	7	0
		Urticarias	62	0
		Urticaria chronic	2	0
	Cornification and dystrophic skin disorders	Skin hypertrophy	1	0
	Epidermal and dermal conditions	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	14	0
		Skin discomfort	1	0
		Skin induration	2	0
		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	96	0
	Exfoliative conditions	Exfoliative rash	1	0
		Skin exfoliation	2	0
	Papulosquamous conditions	Pityriasis rosea	3	0
	Photosensitivity and photodermatitis conditions	Photosensitivity reaction	3	0
	Pruritus NEC	Pruritus	58	0
	Rashes, eruptions and exanthems NEC	Rash	149	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
	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	50	0
		Night sweats	3	0
Skin vascular abnormalities	Purpura and related conditions	Ecchymosis	1	0
		Henoch-Schonlein purpura	2	0
		Petechiae	2	0
		Purpura	3	0
	Skin vasculitides	Cutaneous vasculitis	1	0
	Skin vasomotor conditions	Livedo reticularis	6	0
<b>Total</b>			<b>624</b>	<b>0</b>
Social circumstances	Lifestyle issues	Disability issues	2	0
		Impaired work ability	2	0

			Loss of personal independence in daily activities	1	0
	<b>Total</b>			<b>3</b>	<b>0</b>
Surgical and medical procedures	Obstetric and gynaecological therapeutic procedures	Induced abortions	Abortion induced	4	0
		Obstetric therapeutic procedures	Caesarean section	3	0
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Vacuum extractor delivery	1	0
			Interchange of vaccine products	1	0
	<b>Total</b>			<b>9</b>	<b>0</b>
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	8	0
		Vascular hypotensive disorders	Shock	3	0
			Hypotension	25	0
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Orthostatic hypotension	1	0
			Thrombosis	1	0
	Lymphatic vessel disorders	Lymphoedemas	Thrombophlebitis	2	0
			Lymphoedema	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	6	0
			Flushing	21	0
			Hot flush	4	0
			Pallor	111	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
	<b>Total</b>			<b>208</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>				<b>8,062</b>	
<b>TOTAL REPORTS</b>				<b>2,466</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>					<b>5</b>