

Pneumovax II and Pneumovax 23 Vaccine Analysis Print. All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with **least one of the following vaccines: "Pneumovax II", "Pneumovax 23"**, up to and including 14/05/2025. Report run: 15/05/2025 Earliest reaction date: 23/11/1979

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	3	0
		Marrow depression and hypoplastic anaemias	Aplastic anaemia	1	0
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Increased tendency to bruise	1	0
		Coagulopathies	Factor VIII inhibition	1	0
	Haemoglobinopathies	Sickle cell trait and disorders	Sickle cell anaemia with crisis	2	0
	Haemolyses and related conditions	Anaemias haemolytic immune	Coombs positive haemolytic anaemia	1	0
		Anaemias haemolytic NEC	Haemolytic anaemia	1	0
		Haemolyses NEC	Haemolysis	2	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	1	0
			Thrombocytopenia	3	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	4	0
			Lymphadenitis	2	0
			Lymphadenopathy	38	0
			Lymphadenopathy mediastinal	1	0
		Spleen disorders	Splenomegaly	1	0
	White blood cell disorders	Eosinophilic disorders	Eosinophilia	2	0
		Neutropenias	Agranulocytosis	1	0
			Febrile neutropenia	1	0
			Neutropenia	1	0
	Total			67	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	3	0
			Cardiac flutter	1	0
			Tachycardia	14	0
		Supraventricular	Atrial fibrillation	6	0

		arrhythmias	Sinus tachycardia	1	0	
			Supraventricular tachycardia	2	0	
		Ventricular arrhythmias and cardiac arrest	Ventricular extrasystoles	1	0	
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiac disorder	1	0	
		Cardiac signs and symptoms NEC	Palpitations	14	0	
	Coronary artery disorders	Coronary artery disorders NEC	Arteriosclerosis coronary artery	1	0	
			Coronary artery disease	1	0	
			Coronary artery thrombosis	1	0	
		Ischaemic coronary artery disorders	Angina pectoris	2	0	
			Myocardial infarction	4	3	
			Myocardial ischaemia	4	1	
	Heart failures	Heart failure signs and symptoms	Peripheral swelling	1	0	
		Heart failures NEC	Cardiac failure acute	1	1	
			Ventricular failure	1	0	
		Left ventricular failures	Left ventricular failure	1	0	
	Myocardial disorders	Myocardial disorders NEC	Myocardial fibrosis	1	0	
		Noninfectious myocarditis	Myopericarditis	1	0	
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	1	0	
		Pericardial disorders NEC	Cardiac tamponade	1	0	
	Total			64	5	
	Congenital, familial and genetic disorders	Blood and lymphatic system disorders congenital	Haemoglobinopathies congenital	Sickle cell anaemia	1	0
		Cardiac and vascular disorders congenital	Cardiac septal defects congenital	Ventricular septal defect	1	0

	Renal and urinary tract disorders congenital	Renal and urinary tract disorders congenital NEC	Urinary tract malformation	1	0
	Total			3	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear congestion	1	0
			Ear disorder	1	0
			Ear pain	3	0
	Hearing disorders	Hearing losses	Deafness	2	0
			Deafness neurosensory	1	0
			Deafness unilateral	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Meniere's disease	1	0
			Tinnitus	7	0
			Vertigo	8	0
	Total			25	0
Endocrine disorders	Adrenal gland disorders	Adrenal cortical hypofunctions	Adrenocortical insufficiency acute	1	0
	Total			1	0
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye disorder	1	0
			Eye oedema	1	0
			Eye pain	4	0
			Eye swelling	1	0
			Periorbital oedema	2	0
			Periorbital swelling	1	0
			Vitreous disorder	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Swelling of eyelid	1	0
		Ocular infections, inflammations and associated manifestations	Eye pruritus	1	0
			Limbal swelling	1	0
			Ocular hyperaemia	1	0
		Retinal, choroid and vitreous infections and inflammations	Necrotising retinitis	1	0

		Scleral infections, irritations and inflammations	Scleritis	1	0
Ocular neuromuscular disorders	Ocular nerve and muscle disorders		Eye movement disorder	2	0
	Pupil disorders		Mydriasis	1	0
Ocular sensory symptoms NEC	Ocular sensation disorders		Photophobia	10	0
Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit and degeneration		Vitreous floaters	1	0
	Orbital structural change, deposit and degeneration		Orbital oedema	1	0
Vision disorders	Refractive and accommodative disorders		Hypermetropia	1	0
	Visual disorders NEC		Diplopia	2	0
			Photopsia	2	0
			Vision blurred	7	0
	Visual field disorders		Visual field defect	1	0
	Visual impairment and blindness (excl colour blindness)		Blindness	1	0
			Visual acuity reduced	1	0
	Visual pathway disorders		Visual impairment	4	0
Total				52	0
Gastrointestinal disorders	Dental and gingival conditions	Gingival haemorrhages	Gingival bleeding	1	0
	Exocrine pancreas conditions	Acute and chronic pancreatitis	Pancreatitis	1	1
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis ulcerative	1	0
			Crohn's disease	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	31	0
		Gastrointestinal atonic	Constipation	2	0

	and hypomotility disorders NEC	Gastrooesophageal reflux disease	2	0
	Gastrointestinal spastic and hypermotility disorders	Irritable bowel syndrome	1	0
Gastrointestinal signs and symptoms	Abdominal findings abnormal	Abdominal mass	1	0
	Dyspeptic signs and	Dyspepsia	2	0
		Eructation	1	0
	Faecal abnormalities NEC	Mucous stools	2	0
	Flatulence, bloating and distension	Abdominal distension	2	0
		Flatulence	1	0
	Gastrointestinal and abdominal pains (excluding oral and throat)	Abdominal pain	8	0
		Abdominal pain lower	2	0
		Abdominal pain upper	7	0
		Abdominal tenderness	1	0
	Gastrointestinal signs and symptoms NEC	Abdominal discomfort	7	0
		Anal incontinence	1	0
		Dysphagia	2	0
	Nausea and vomiting	Nausea	143	0
		Vomiting	85	0
Oral soft tissue conditions	Oral soft tissue signs and symptoms	Lip erythema	1	0
		Lip pain	1	0
		Oral mucosal blistering	1	0
		Oral pain	2	0
		Paraesthesia oral	2	0
	Oral soft tissue swelling and	Lip swelling	4	0
		Palatal oedema	1	0
	Stomatitis and ulceration	Mouth ulceration	5	0
		Stomatitis	2	0
Peritoneal and retroperitoneal conditions	Peritoneal and retroperitoneal disorders	Ascites	1	0
	Peritoneal and retroperitoneal haemorrhages	Retroperitoneal haematoma	1	0
Salivary gland conditions	Salivary gland enlargements	Parotid gland enlargement	1	0

General disorders and administration site conditions	Tongue conditions	Tongue disorders	Glossitis	1	0
			Tongue ulceration	2	0
		Tongue signs and symptoms	Swollen tongue	2	0
			Tongue blistering	2	0
			Tongue oedema	1	0
	Total			335	1
	Administration site reactions	Administration site reactions NEC	Administration site inflammation	1	0
			Administration site pain	1	0
			Administration site rash	1	0
			Administration site swelling	1	0
		Application site reactions	Application site erythema	1	0
		Injection site reactions	Injected limb mobility decreased	12	0
			Injection site abscess sterile	1	0
			Injection site atrophy	1	0
			Injection site bruising	1	0
			Injection site discolouration	2	0
			Injection site erythema	82	0
			Injection site haematoma	2	0
			Injection site haemorrhage	1	0
			Injection site hypersensitivity	2	0
			Injection site induration	6	0
			Injection site inflammation	66	0
			Injection site joint movement impairment	1	0

Injection site joint swelling	1	0
Injection site joint warmth	1	0
Injection site mass	10	0
Injection site movement impairment	3	0
Injection site necrosis	2	0
Injection site oedema	4	0
Injection site pain	106	0
Injection site pruritus	8	0
Injection site rash	15	0
Injection site reaction	108	0
Injection site scar	3	0
Injection site swelling	64	0
Injection site ulcer	3	0
Injection site urticaria	2	0
Injection site vesicles	3	0
Injection site warmth	20	0
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	4	0
Vaccination site discolouration	1	0
Vaccination site discomfort	4	0
Vaccination site erythema	46	0

		Vaccination site induration	5	0
		Vaccination site inflammation	8	0
		Vaccination site irritation	1	0
		Vaccination site joint erythema	2	0
		Vaccination site joint movement impairment	7	0
		Vaccination site joint pain	2	0
		Vaccination site mass	4	0
		Vaccination site movement impairment	6	0
		Vaccination site pain	70	0
		Vaccination site phlebitis	1	0
		Vaccination site pruritus	3	0
		Vaccination site rash	12	0
		Vaccination site reaction	8	0
		Vaccination site scab	1	0
		Vaccination site swelling	56	0
		Vaccination site warmth	26	0
Body temperature conditions	Body temperature altered	Hypothermia	1	0
		Temperature regulation disorder	1	0
	Febrile disorders	Pyrexia	368	0
Fatal outcomes	Death and sudden death	Death	3	3
		Sudden death	1	1
General system disorders NEC	Asthenic conditions	Asthenia	43	0
		Fatigue	99	0
		Malaise	224	0
	Feelings and sensations NEC	Chills	140	0
		Feeling abnormal	17	0
		Feeling cold	21	0
		Feeling drunk	2	0
		Feeling hot	53	0

		Feeling of body temperature change	14	0
		Thirst	2	0
	Gait disturbances	Gait disturbance	6	0
		Gait inability	1	0
		Loss of control of legs	1	0
	General signs and symptoms NEC	Condition aggravated	6	0
		Exercise tolerance decreased	2	0
		Foaming at mouth	1	0
		Illness	16	0
		Induration	7	0
		Influenza like illness	82	0
		Local reaction	157	0
		Multiple organ dysfunction syndrome	1	1
		Peripheral swelling	324	0
		Screaming	1	0
		Swelling	107	0
		Swelling face	6	0
	Inflammation s	Inflammation	62	0
		Systemic inflammatory response syndrome	3	0
	Oedema NEC	Localised oedema	9	0
		Oedema	14	0
		Oedema peripheral	16	0
	Pain and discomfort NEC	Axillary pain	15	0
		Chest discomfort	26	0
		Chest pain	27	0
		Discomfort	8	0
		Facial pain	2	0
		Non-cardiac chest pain	1	0
		Pain	175	0
		Tenderness	25	0
Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	2	0
	Therapeutic and nontherapeutic responses	Adverse drug reaction	28	0
		Drug ineffective	7	0

			Therapeutic response decreased	1	0
			Therapy non-responder	4	0
			Vaccination failure	12	0
	Tissue disorders NEC	Mass conditions NEC	Mass	3	0
			Nodule	1	0
		Necrosis NEC	Necrosis	1	0
		Ulcers NEC	Ulcer	2	0
	Total			2,957	5
Hepatobiliary disorders	Bile duct disorders	Bile duct infections and inflammations	Biliary colic		
				1	0
	Gallbladder disorders	Cholecystitis and cholelithiasis	Cholecystitis	1	0
			Cholelithiasis	2	0
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	3	0
		Hepatic and hepatobiliary disorders NEC	Liver disorder	1	0
		Hepatic failure and associated disorders	Acute hepatic failure	1	1
			Hepatic failure	1	0
			Hepatorenal syndrome	2	0
		Hepatic fibrosis and cirrhosis	Hepatic cirrhosis	1	1
	Hepatocellular damage and hepatitis NEC	Hepatitis	1	0	
		Hepatitis chronic active	1	0	
	Total			15	2
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	45	0
			Serum sickness	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	2	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	15	0
			Anaphylactic shock	5	1
			Anaphylactoid reaction	3	0
	Atopic disorders	Seasonal allergy	1	0	
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder	1	0

	Immune disorders NEC	Blood isoimmune reactions	Alloimmunisation	1	0
		Immune and associated conditions NEC	Bacille Calmette- Guerin scar reactivation	1	0
			Immune system disorder	2	0
	Total			77	1
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Administra- tion site cellulitis	1	0
			Arthritis bacterial	1	0
			Bacterial infection	2	0
			Cellulitis	129	0
			Cellulitis gangrenous	1	0
			Injection site cellulitis	26	0
			Pneumonia bacterial	1	0
			Post procedural cellulitis	1	0
			Vaccination site cellulitis	19	0
		Clostridia infections	Clostridium difficile infection	1	0
			Gas gangrene	1	1
		Haemophilus infections	Haemophilus infection	1	0
			Haemophilus sepsis	1	0
			Septic arthritis haemophilus	1	0
		Neisseria infections	Meningitis meningococ- cal	1	0
			Meningococ- cal sepsis	1	0
		Streptococcal infections	Meningitis pneumococ- cal	7	0
			Pneumococ- cal infection	4	0
			Pneumococ- cal sepsis	1	1
			Pneumonia pneumococ- cal	1	0
			Pneumonia streptococcal	1	1
	Fungal infectious disorders	Tinea infections	Tinea infection	1	0
			Tinea pedis	1	0

Infections - pathogen unspecified	Bone and joint infections	Arthritis infective	1	0
	Central nervous system and	Encephalitis	3	0
		Encephalomyelitis	1	0
	Dental and oral soft tissue infections	Parotitis	1	0
	Ear infections	Ear infection	1	0
		Labyrinthitis	1	0
		Otitis media acute	1	0
		Otitis media chronic	1	0
	Eye and eyelid infections	Conjunctivitis	1	0
	Infections NEC	Abscess	6	0
		Abscess limb	1	0
		Infection	9	0
		Injection site abscess	2	0
		Localised infection	2	0
		Respiratory tract infection	3	0
		Systemic infection	1	0
		Vaccination site abscess	1	0
		Vaccination site infection	1	0
	Lower respiratory tract and lung infections	Bronchitis	6	0
		Lower respiratory tract infection	18	0
		Pneumonia	30	6
	Male reproductive tract infections	Orchitis	1	0
	Sepsis, bacteraemia, viraemia and fungaemia NEC	Bacteraemia	1	0
		Sepsis	9	0
		Septic shock	2	0
	Skin structures and soft tissue infections	Carbuncle	1	0
		Skin infection	1	0
		Subcutaneous abscess	1	0
	Upper respiratory tract infections	Laryngitis	2	0
		Nasopharyngitis	9	0
		Rhinitis	2	0

Injury, poisoning and procedural complications		Urinary tract infections	Urinary tract infection	4	0
		Vascular infections	Lymphangitis	5	0
	Mycobacterial infectious disorders	Tuberculous infections	Erythema induratum	9	0
	Viral infectious disorders	Hepatitis virus infections	Hepatitis A	1	0
		Herpes viral infections	Herpes zoster	7	0
			Oral herpes	2	0
			Varicella zoster virus infection	1	0
		Influenza viral infections	Influenza	7	0
		Viral infections NEC	Gastroenteritis viral	1	0
			Viral infection	2	0
			Viral rash	1	0
	Total			364	9
	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	3	0
			Foetal exposure during pregnancy	2	0
			Maternal exposure during pregnancy	1	0
	Injuries by physical agents	Heat injuries (excl thermal burns)	Heat oedema	1	0
	Injuries NEC	Cardiovascular injuries	Vascular injury	1	0
		Nerve injuries NEC	Nerve injury	1	0
		Non-site specific injuries NEC	Fall	1	0
			Wound secretion	1	0
		Skin injuries NEC	Contusion	16	0
			Scar	2	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Circumstance or information capable of leading to medication error	1	0
			Medication error	26	0
			Product use issue	1	0
			Vaccination error	1	0

Investigations			Wrong technique in product usage process	1	0
	Product administration errors and issues		Inappropriate schedule of product administration	5	0
			Incorrect route of product administration	1	0
			Product administered at inappropriate site	5	0
			Product administered to patient of inappropriate age	1	0
			Product administration error	3	0
			Wrong product administered	2	0
	Product prescribing errors and issues		Product prescribing error	1	0
	Off label uses and intentional product misuses/use issues	Off label uses	Off label use	3	0
	Procedural related injuries and complications NEC	Non-site specific procedural complications	Injection related reaction	5	0
			Wound decomposition	1	0
		Vaccination related complications	Immunisation reaction	4	0
			Vaccination complication	1	0
	Total			91	0
	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	1	0
		Heart rate and pulse investigations	Heart rate	1	0
			Heart rate increased	13	0
			Heart rate irregular	2	0
	Vascular tests NEC (incl blood		Blood pressure abnormal	1	0

	pressure)	Blood pressure decreased	1	0
		Blood pressure increased	6	0
Cytogenetic investigations and genetic analyses	Cell marker analyses	Prostatic specific antigen increased	1	0
Enzyme investigations NEC	Skeletal and cardiac muscle analyses	Blood creatine phosphokinase increased	2	0
Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	Fibrin D dimer increased	1	0
		International normalised ratio increased	2	0
	Haematological analyses NEC	Red blood cell sedimentation rate increased	1	0
	Platelet analyses	Platelet count decreased	1	0
	White blood cell analyses	Neutrophil count increased	1	0
		White blood cell count increased	4	0
Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	1	0
		Liver function test abnormal	1	0
Immunology and allergy investigations	Autoimmunity analyses	Antinuclear antibody positive	1	0
	Immunology analyses NEC	Antibody test abnormal	1	0
		Antibody test negative	2	0
Lipid analyses	Cholesterol analyses	High density lipoprotein decreased	1	0
Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	6	0
		Blood glucose decreased	3	0
	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose fluctuation	1	0

Metabolism and nutrition disorders			Blood glucose increased	2	0
		Metabolism tests NEC	Blood ketone body	1	0
	Microbiology and serology investigations	Bacteria identification and serology (excl mycobacteria)	Streptococcus test positive	2	0
		Microbiology and serology tests NEC	Seroconversion test negative	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature	1	0
			Body temperature abnormal	1	0
			Body temperature fluctuation	1	0
			Body temperature increased	37	0
			Grip strength decreased	1	0
			Respiratory rate increased	1	0
			Weight decreased	2	0
	Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	2	0
		Protein analyses NEC	C-reactive protein increased	3	0
	Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine increased	2	0
		Urinalysis NEC	Blood urine present	1	0
			Protein urine present	1	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood potassium increased	1	0
			Blood sodium decreased	1	0
	Total			116	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	46	0
			Hypophagia	1	0
		General nutritional disorders NEC	Abnormal loss of weight	1	0
			Feeding disorder	1	0

Musculoskeletal and connective tissue disorders	Electrolyte and fluid balance conditions	Fluid intake increased	Polydipsia	1	0
		Potassium imbalance	Hyperkalaemia	1	0
		Total fluid volume decreased	Dehydration	5	0
		Total fluid volume increased	Fluid retention	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Diabetes mellitus	1	0
			Diabetes mellitus inadequate control	6	0
			Type 2 diabetes mellitus	1	0
		Hypoglycaemic conditions NEC	Hypoglycaemia	2	0
	Purine and pyrimidine metabolism disorders	Disorders of purine metabolism	Gout	2	0
	Total			69	0
	Bone disorders (excl congenital and fractures)	Bone disorders NEC	Osteonecrosis	1	0
			Bone pain	3	0
			Bone swelling	1	0
			Pain in jaw	3	0
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Myofascitis	1	0
			Polymyalgia rheumatica	3	0
		Lupus erythematosus (incl subtypes)	Systemic lupus erythematosus	1	0
	Joint disorders	Arthropathies NEC	Arthritis	6	0
			Arthropathy	3	0
			Polyarthritis	5	0
			Seronegative arthritis	1	0
		Joint related disorders NEC	Joint lock	1	0
			Periarthritis	12	0
			Rotator cuff syndrome	2	0
			Temporomandibular pain and dysfunction syndrome	1	0
		Joint related signs and symptoms	Arthralgia	133	0
			Joint effusion	1	0
			Joint stiffness	4	0
			Joint swelling	23	0

	Osteoarthropathies	Osteoarthritis	2	0
	Rheumatoid arthropathies	Rheumatoid arthritis	4	0
	Spondyloarthropathies	Arthritis reactive	1	0
Muscle disorders	Muscle infections and inflammations	Myositis	6	0
	Muscle pains	Myalgia	113	0
	Muscle related signs and symptoms NEC	Muscle atrophy	1	0
		Muscle disorder	1	0
		Muscle fatigue	5	0
		Muscle mass	1	0
		Muscle spasms	8	0
		Muscle swelling	2	0
		Muscle tightness	1	0
		Muscle twitching	1	0
	Muscle weakness conditions	Muscular weakness	22	0
	Myopathies	Myopathy	1	0
		Rhabdomyolysis	1	0
Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Limb mass	1	0
		Mobility decreased	9	0
		Musculoskeletal stiffness	40	0
		Weight bearing difficulty	29	0
	Musculoskeletal and connective tissue pain and discomfort	Back pain	25	0
		Limb discomfort	16	0
		Musculoskeletal chest pain	4	0
		Musculoskeletal discomfort	2	0
		Musculoskeletal pain	2	0
		Neck pain	16	0
		Pain in extremity	291	0
	Soft tissue disorders NEC	Neck mass	1	1
		Soft tissue disorder	1	0
Synovial and bursal disorders	Bursal disorders	Bursitis	6	0
	Synovial disorders	Synovitis	1	0

	Tendon, ligament and cartilage disorders	Tendon disorders	Tendon disorder	1	0
	Total			820	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasms malignant and unspecified (incl nipple)	Breast and nipple neoplasms malignant	Intraductal proliferative breast lesion	1	0
			Invasive ductal breast carcinoma	1	0
	Lymphomas NEC	Lymphomas unspecified NEC	Lymphoma	2	1
	Mesotheliomas	Mesothelioma as malignant and unspecified	Mesothelioma	1	0
	Metastases	Metastases to specified sites	Metastases to bone	1	0
	Respiratory and mediastinal neoplasms malignant and unspecified	Non-small cell neoplasms malignant of the respiratory tract cell type specified	Lung adenocarcinoma stage IV	1	1
	Total			7	2
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	Cerebrovascular accident	6	2
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Facial paralysis	1	0
			Facial paresis	2	0
		Optic nerve disorders NEC	Optic neuritis	1	0
	Demyelinating disorders	Demyelinating disorders NEC	Acute disseminated encephalomyelitis	1	1
		Multiple sclerosis acute and progressive	Multiple sclerosis	1	0
	Headaches	Headaches NEC	Cluster headache	1	0
			Headache	178	0

		Sinus headache	1	0
		Tension headache	2	0
		Vascular headache	1	0
	Migraine headaches	Migraine	5	0
		Migraine with aura	2	0
Mental impairment disorders	Memory loss (excl dementia)	Amnesia	1	0
		Memory impairment	1	0
	Mental impairment (excl dementia and memory)	Disturbance in attention	5	0
		Mental impairment	1	0
Movement disorders (incl parkinsonism)	Choreiform movements	Choreoathetosis	1	0
	Dyskinesias and movement disorders NEC	Bradykinesia	1	0
		Hypokinesia	13	0
		Movement disorder	4	0
	Paralysis and paresis (excl cranial nerve)	Hemiparesis	2	0
		Hemiplegia	1	0
		Monoplegia	5	0
		Paralysis	3	0
	Parkinson's disease and parkinsonism	Cogwheel rigidity	1	0
		Parkinson's disease	1	0
	Tremor (excl congenital)	Tremor	28	0
Neurological disorders NEC	Coordination and balance disturbances	Ataxia	2	0
		Balance disorder	7	0
		Dysstasia	1	0
	Cortical dysfunction NEC	Aphasia	1	0
	Disturbances in consciousness NEC	Lethargy	29	0
		Loss of consciousness	12	0
		Somnolence	22	0
		Stupor	2	0
		Syncope	28	0
	Nervous system disorders NEC	Nervous system disorder	1	0
	Neurological signs and symptoms NEC	Dizziness	71	0
		Dizziness postural	5	0
		Head discomfort	2	0
		Hyporesponsive to stimuli	1	0
		Meningism	1	0

			Myoclonus	1	0
			Neurological symptom	1	0
			Presyncope	3	0
			Slow response to stimuli	1	0
			Unresponsive to stimuli	1	0
		Paraesthesias and dysaesthesias	Burning sensation	7	0
			Hyperaesthesia	2	0
			Hypoaesthesia	24	0
			Paraesthesia	41	0
		Sensory abnormalities NEC	Ageusia	1	0
			Allodynia	1	0
			Electric shock sensation	1	0
			Neuralgia	8	0
			Sensory disturbance	5	0
			Sensory loss	3	0
		Speech and language abnormalities	Dysarthria	4	0
			Slow speech	2	0
			Speech disorder	1	0
	Neurological disorders of the eye	Neurologic visual problems NEC	Tunnel vision	1	0
	Neuromuscular disorders	Motor neurone diseases	Motor neurone disease	1	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	13	2
		Chronic polyneuropathies	Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
			Diabetic neuropathy	1	0
		Mononeuropathies	Nerve compression	1	0
			Peroneal nerve palsy	1	0
		Peripheral neuropathies NEC	Brachial plexopathy	1	0
			Neuralgic amyotrophy	2	0
			Neuritis	1	0
			Neuropathy peripheral	1	0

		Polyneuropathy	2	0
	Seizures (incl subtypes)	Generalised tonic-clonic seizures	2	0
		Seizures and seizure disorders NEC	Epilepsy	3
			Febrile convulsion	1
			Seizure	7
			Status epilepticus	1
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	1
	Spinal cord and nerve root disorders	Spinal cord and nerve root disorders	Radiculitis brachial	2
			Radiculopathy	1
	Total		608	5
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions spontaneous	Abortion spontaneous	1
	Foetal complications	Foetal complications NEC	Foetal distress syndrome	1
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature delivery	1
		Maternal complications of delivery NEC	Complication of delivery	1
	Maternal complications of pregnancy	Maternal complications of pregnancy NEC	Hyperemesis gravidarum	1
	Neonatal and perinatal conditions	Neonatal hepatobiliary disorders	Jaundice neonatal	1
	Total		6	0
Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Product contamination and sterility issues	Product contamination microbial	1
		Product quality issues NEC	Product origin unknown	1
			Product quality issue	1
	Total		3	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	1
			Anxiety	3
			Nervousness	2
	Changes in physical activity	Decreased physical activity levels	Catatonia	1

Deliria (incl confusion)	Confusion and disorientation	Confusional state	7	0
		Disorientation	5	0
	Deliria	Delirium	4	0
		Delirium tremens	1	0
Depressed mood disorders and disturbances	Depressive disorders	Depression	3	0
	Mood alterations with depressive symptoms	Depressed mood	1	0
		Depressive symptom	1	0
		Tearfulness	1	0
Dissociative disorders	Dissociative states	Dissociation	1	0
Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	3	0
	Thinking disturbances	Thinking abnormal	1	0
Eating disorders and disturbances	Eating disorders NEC	Binge eating	1	0
		Eating disorder	1	0
Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Anger	1	0
		Irritability	2	0
		Mood altered	1	0
	Mood disorders NEC	Listless	1	0
Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Paranoia	1	0
		Social avoidant behaviour	1	0
Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	1	0
Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Psychotic disorder	2	0
Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	14	0
	Dyssomnias	Poor quality sleep	2	0
	Parasomnias	Abnormal dreams	1	0
		Nightmare	1	0
	Sleep disorders NEC	Sleep disorder	3	0
Total			68	0
Bladder and bladder neck disorders (excl calculi)	Bladder disorders NEC	Bladder obstruction	1	0

Reproductive system and breast disorders	Nephropathies	Glomerulonephritis and nephrotic syndrome	Focal segmental glomerulosclerosis	1	0
			Glomerulonephritis rapidly progressive	1	0
			Nephrotic syndrome	3	0
		Nephritis NEC	Lupus nephritis	1	0
			Tubulointerstitial nephritis	1	0
		Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	7
	Chronic kidney disease			1	0
	Renal impairment			1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Dysuria	3	0
			Incontinence	1	0
			Micturition urgency	1	0
			Pollakiuria	5	0
			Urinary incontinence	2	0
			Urinary retention	1	0
		Urinary abnormalities	Chromaturia	1	0
			Proteinuria	1	0
		Urinary tract signs and symptoms	Polyuria	1	0
			Renal pain	1	0
	Total			34	0
	Breast disorders	Breast disorders NEC	Breast mass	1	0
Breast pain			4	0	
Breast swelling			1	0	
Female reproductive tract infections and inflammations		Vaginal and vulval infections and inflammations	Vulvovaginal inflammation	1	0
Reproductive tract disorders NEC		Reproductive tract signs and symptoms NEC	Genital rash	1	0
Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular disorder	1	0	
Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vulval ulceration	1	0	

Respiratory, thoracic and mediastinal disorders	inflammations)	Vulvovaginal signs and symptoms	Vulvovaginal burning sensation	1	0
			Vulvovaginal erythema	1	0
	Total			12	0
	Bronchial disorders (excl neoplasms)	Bronchial conditions NEC	Bronchiectasis	3	0
			Asthma	15	2
			Bronchospasm	5	0
			Wheezing	16	0
	Lower respiratory tract disorders (excl obstruction and infection)	Lower respiratory tract inflammatory and immunologic conditions	Pulmonary eosinophilia	1	0
			Emphysema	1	0
			Organising pneumonia	1	0
			Pulmonary fibrosis	7	2
		Pulmonary oedemas	Acute pulmonary oedema	1	0
	Pleural disorders	Pleural conditions NEC	Pleural thickening	1	0
			Pleurisy	1	0
			Pneumothorax and pleural effusions	6	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	52	0
			Dyspnoea exertional	1	0
			Hyperventilation	1	0
			Respiratory arrest	1	0
			Respiratory distress	2	0
		Conditions associated with abnormal gas exchange	Hypoxia	1	0
		Coughing and associated symptoms	Cough	57	0
			Haemoptysis	1	0
			Productive cough	8	0
			Sputum discoloured	1	0

		Respiratory failures (excl neonatal)	Respiratory failure	1	1
		Respiratory tract disorders NEC	Lung disorder	1	0
			Respiratory tract congestion	1	0
Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms		Increased bronchial secretion	2	0
			Pleuritic pain	1	0
			Pulmonary pain	1	0
	Upper respiratory tract signs and symptoms		Aphonia	1	0
			Catarrh	2	0
			Choking	1	0
			Dry throat	1	0
			Dysphonia	3	0
			Increased viscosity of upper respiratory secretion	1	0
			Nasal discomfort	1	0
			Oropharyngeal pain	20	0
			Rhinorrhoea	8	0
			Sneezing	2	0
			Throat irritation	1	0
			Throat tightness	5	0
			Upper-airway cough syndrome	1	0
Upper respiratory tract disorders (excl infections)		Nasal congestion and inflammations	Nasal congestion	4	0
		Nasal disorders NEC	Epistaxis	2	0
		Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	1	0
		Pharyngeal disorders (excl infections and	Pharyngeal swelling	3	0
			Tonsillar inflammation	1	0
	Total			248	5
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	2	0
		Urticarias	Urticaria	57	0

		Urticaria papular	1	0
		Urticarial vasculitis	1	0
Cornification and dystrophic skin disorders	Skin dystrophies	Skin wrinkling	2	0
Epidermal and dermal conditions	Bullous conditions	Blister	3	0
		Erythema multiforme	1	0
		Stevens-Johnson syndrome	2	0
		Toxic epidermal necrolysis	1	0
	Dermal and epidermal conditions NEC	Acute febrile neutrophilic dermatosis	1	0
		Dry skin	3	0
		Pain of skin	9	0
		Sensitive skin	1	0
		Skin burning sensation	2	0
		Skin discolouration	7	0
		Skin disorder	2	0
		Skin induration	14	0
		Skin lesion	3	0
		Skin necrosis	1	0
		Skin reaction	15	0
		Skin sensitisation	1	0
		Skin swelling	1	0
		Skin tightness	3	0
		Skin warm	35	0
	Dermatitis and eczema	Dermatitis	4	0
		Dermatitis allergic	7	0
		Eczema	4	0
		Skin irritation	4	0
	Erythemas	Erythema	288	0
	Exfoliative conditions	Skin exfoliation	7	0
	Papulosquamous conditions	Parapsoriasis	1	0
	Pruritus NEC	Pruritus	43	0
	Psoriatic conditions	Erythrodermic psoriasis	1	0
		Guttate psoriasis	1	0

	Rashes, eruptions and exanthems NEC	Rash	Rash	63	0
		Rash erythematous		32	0
		Rash macular		18	0
		Rash maculopapular		3	0
		Rash papular		9	0
		Rash pruritic		7	0
	Skin injuries and mechanical dermatoses	Needle track marks		1	0
	Skin and subcutaneous tissue disorders NEC	Panniculitides	Erythema nodosum	2	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	5	0
			Hyperhidrosis	48	0
			Night sweats	8	0
		Nail and nail bed conditions (excl infections and infestations)	Nail discolouration	1	0
		Pilar disorders NEC	Hair texture abnormal	1	0
	Skin vascular abnormalities	Purpura and related conditions	Henoch-Schonlein purpura	4	0
			Petechiae	1	0
		Skin vasculitides	Vasculitic rash	4	0
		Skin vasomotor conditions	Livedo reticularis	1	0
	Total			736	0
Social circumstances	Lifestyle issues	Disability issues	Bedridden	1	0
			Immobile	3	0
			Loss of personal independence in daily activities	1	0
		Social issues NEC	Contraindication to vaccination	2	0
	Total			7	0
Surgical and medical procedures	Bone and joint therapeutic procedures	Limb therapeutic procedures	Limb immobilisation	5	0
	Haematological and lymphoid tissue therapeutic procedures	Blood and blood product treatment	Transfusion	1	0

	Head and neck therapeutic procedures	Inner ear therapeutic procedures	Cochlea implant	1	0
	Obstetric and gynaecological therapeutic procedures	Obstetric therapeutic procedures	Caesarean section	1	0
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Medical device removal	1	0
			Rest regimen	1	0
	Total			10	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	10	0
	Decreased and nonspecific blood pressure disorders and shock	Blood pressure disorders NEC	Blood pressure fluctuation	1	0
		Circulatory collapse and shock	Circulatory collapse	11	1
			Shock	2	0
		Vascular hypotensive disorders	Hypotension	15	0
			Orthostatic hypotension	2	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	3	0
			Flushing	12	0
			Hot flush	4	0
		Site specific vascular disorders NEC	Pallor	7	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	3	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	7	0
	Vascular infections and inflammations	Vasculitides NEC	Behcet's syndrome	1	0
			Vasculitis	2	0
	Total			80	1
TOTAL REACTIONS FOR DRUG				6,875	
TOTAL REPORTS				2,359	
TOTAL FATAL OUTCOME REPORTS					37