

## Tirzepatide Drug Analysis Print

All UK spontaneous ADR reports received between 20/05/2024 up to and including 06/12/2024

Run date 09/12/2024

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemia deficiencies	Pernicious anaemia	1	0
		Anaemias NEC	Anaemia	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	6	0
			Lymphadenopathy	13	0
	White blood cell disorders	Eosinophilic disorders	Eosinophilia	2	0
	Cardiac arrhythmias	Cardiac conduction disorders	Atrioventricular block	1	0
		Rate and rhythm disorders NEC	Arrhythmia	3	0
			Cardiac flutter	3	0
			Extrasystoles	1	0
			Postural orthostatic tachycardia syndrome	1	0
			Tachycardia	16	0

Cardiac disorders		Supraventricular arrhythmias	Atrial fibrillation	4	0
			Atrial flutter	1	0
			Supraventricular tachycardia	2	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	4	1
			Ventricular tachycardia	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	96	0
	Coronary artery disorders	Ischaemic coronary artery disorders	Acute myocardial infarction	2	0
			Myocardial infarction	7	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear congestion	1	0
			Ear pain	2	0
	Hearing disorders	Hearing losses	Hypoacusis	3	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Motion sickness	1	0
			Tinnitus	6	0
			Vertigo	4	0

Endocrine disorders	Thyroid gland disorders	Thyroid disorders NEC	Goitre	3	0
			Thyroid disorder	1	0
			Thyroid mass	4	0
		Thyroid hypofunction disorders	Hypothyroidism	2	0
		Thyroid neoplasms	Thyroid cyst	1	0
	Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	1	0
	Eye disorders NEC	Lacrimation disorders	Dry eye	4	0
		Ocular disorders NEC	Eye disorder	1	0
			Eye pain	3	0
			Eye swelling	1	0
			Periorbital swelling	2	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Blepharitis	1	0
		Ocular infections, inflammations and associated manifestations	Eye pruritus	2	0
	Ocular neuromuscular	Eyelid movement	Blepharospasm	1	0

Eye disorders	neuromuscular disorders	movement disorders	Eyelid ptosis	1	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	1	0
	Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit and	Vitreous floaters	1	0
		Retinal structural change, deposit and degeneration	Maculopathy	2	0
			Retinal detachment	2	0
	Retina, choroid and vitreous haemorrhages and vascular disorders	Retinal bleeding and vascular disorders (excl retinopathy)	Retinal ischaemia	1	0
		Retinopathies NEC	Diabetic retinopathy	1	0
			Retinopathy	1	0
	Vision disorders	Refractive and accommodative disorders	Myopia	1	0
		Visual disorders NEC	Diplopia	2	0
			Vision blurred	29	0
		Visual impairment and blindness (excl colour blindness)	Blindness	5	0
			Blindness unilateral	1	0
			Visual impairment	7	0

	Abdominal hernias and other abdominal wall conditions	Umbilical hernias	Umbilical hernia	1	0
	Dental and gingival conditions	Dental pain and sensation disorders	Hyperaesthesia teeth	1	0
			Toothache	2	0
		Gingival disorders, signs and symptoms NEC	Gingival pain	1	0
	Exocrine pancreas conditions	Acute and chronic pancreatitis	Haemorrhagic necrotic pancreatitis	1	1
			Obstructive pancreatitis	2	0
			Pancreatitis	50	1
			Pancreatitis acute	14	0
		Cystic pancreatic disorders	Pancreatic cyst	2	0
		Pancreatic disorders NEC	Pancreatic disorder	1	0
			Pancreatic failure	1	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Food poisoning	2	0
			Gastrointestinal disorder	10	0
		Oesophageal disorders NEC	Oesophageal disorder	1	0

Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Gastric haemorrhage	1	0
	Intestinal haemorrhages	Rectal haemorrhage	8	0
	Non-site specific gastrointestinal haemorrhages	Haematemesis	7	0
		Haematochezia	4	0
Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis	4	0
		Colitis ischaemic	1	0
	Gastritis (excl infective)	Gastritis	14	0
		Reflux gastritis	2	0
	Gastrointestinal inflammatory disorders NEC	Duodenitis	1	0
		Mesenteric panniculitis	1	0
	Oesophagitis (excl infective)	Oesophagitis	2	0
	Diarrhoea (excl infective)	Diarrhoea	1,306	0
		Diarrhoea haemorrhagic	3	0
		Constipation	1,699	0

Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Gastrointestinal atonic and hypomotility disorders NEC	Gastrooesophageal reflux disease	35	0
			Impaired gastric emptying	12	0
			Intestinal pseudo-obstruction	1	0
		Gastrointestinal dyskinetic disorders	Bowel movement irregularity	1	0
			Gastrointestinal motility disorder	1	0
		Gastrointestinal spastic and hypermotility disorders	Oesophageal spasm	1	0
		Abdominal findings abnormal	Gastrointestinal sounds abnormal	2	0
		Dyspeptic signs and symptoms	Dyspepsia	77	0
			Epigastric discomfort	1	0
			Eructation	121	0
		Faecal abnormalities NEC	Abnormal faeces	2	0
			Faecaloma	1	0
			Faeces discoloured	3	0
		Flatulence, bloating and	Abdominal distension	63	0

Gastrointestinal signs and symptoms	Breathing and distension	Flatulence	55	0
	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	419	0
		Abdominal pain lower	7	0
		Abdominal pain upper	116	0
		Gastrointestinal pain	11	0
		Oesophageal pain	1	0
	Gastrointestinal signs and symptoms NEC	Abdominal discomfort	21	0
		Anal incontinence	2	0
		Breath odour	4	0
		Dysphagia	4	0
	Nausea and vomiting symptoms	Discoloured vomit	1	0
		Nausea	2,400	0
		Regurgitation	1	0
		Retching	1	0

		Vomiting	552	0
		Vomiting projectile	4	0
Gastrointestinal stenosis and obstruction	Duodenal and small intestinal stenosis and obstruction	Small intestinal obstruction	2	0
	Gastrointestinal stenosis and obstruction NEC	Intestinal obstruction	5	0
Gastrointestinal ulceration and perforation	Gastric ulcers and perforation	Haemorrhagic erosive gastritis	1	0
	Intestinal ulcers and perforation NEC	Large intestinal ulcer	1	0
	Oesophageal ulcers and perforation	Oesophageal rupture	2	0
	Peptic ulcers and perforation	Peptic ulcer haemorrhage	1	0
Gastrointestinal vascular conditions	Gastrointestinal vascular occlusion and infarction	Intestinal ischaemia	3	1
	Haemorrhoids and gastrointestinal varices (excl oesophageal)	Haemorrhoids	1	0
Malabsorption conditions	Malabsorption syndromes	Steatorrhoea	2	0
	Oral soft tissue disorders NEC	Lip blister	2	0
		Anaesthesia oral	1	0
		Hypoaesthesia oral	2	0

	Oral soft tissue conditions	Oral soft tissue signs and symptoms	Oral discomfort	1	0
			Oral pain	1	0
			Paraesthesia oral	5	0
		Oral soft tissue swelling and oedema	Lip swelling	3	0
		Stomatitis and ulceration	Aphthous ulcer	1	0
			Mouth ulceration	1	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	20	0
			Lip dry	1	0
		Salivary gland disorders NEC	Salivary gland mass	1	0
	Tongue conditions	Tongue signs and symptoms	Glossodynia	2	0
			Swollen tongue	4	0
			Tongue coated	1	0
		Infusion site reactions	Infusion site urticaria	1	0
			Injection site bruising	20	0

Administration  
site reactions

Injection site  
reactions

Injection site discomfort	1	0
Injection site dryness	1	0
Injection site erythema	20	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	1	0
Injection site hypoaesthesia	1	0
Injection site inflammation	2	0
Injection site injury	5	0
Injection site mass	6	0
Injection site oedema	1	0
Injection site pain	15	0
Injection site pruritus	29	0
Injection site rash	36	0
Injection site reaction	26	0

		Injection site swelling	5	0
		Injection site urticaria	6	0
		Injection site vesicles	1	0
		Injection site warmth	2	0
Body temperature conditions	Febrile disorders	Pyrexia	18	0
Complications associated with device	Complications associated with device NEC	Complication associated with device	1	0
		Injury associated with device	1	0
Fatal outcomes	Death and sudden death	Death	4	4
		Hanging	1	1
	Asthenic conditions	Asthenia	13	0
		Fatigue	1,290	0
		Malaise	31	0
		Chills	9	0
		Feeling abnormal	8	0

General disorders and administration site conditions		Feelings and sensations NEC	Feeling cold	24	0
			Feeling hot	7	0
			Feeling jittery	1	0
			Feeling of body temperature change	1	0
			Hunger	10	0
			Sensation of foreign body	13	0
			Thirst	8	0
			Thirst decreased	2	0
		Gait disturbances	Gait disturbance	3	0
			Loss of control of legs	1	0
	General system disorders NEC		Condition aggravated	2	0
			Crying	4	0
			Fat tissue decreased	1	0
			General physical health deterioration	1	0

		General signs and symptoms NEC	Illness	56	0
			Influenza like illness	6	0
			Multiple organ dysfunction syndrome	1	0
			Peripheral swelling	5	0
			Swelling	12	0
			Swelling face	5	0
		Oedema NEC	Oedema	1	0
			Oedema peripheral	2	0
		Pain and discomfort NEC	Chest discomfort	9	0
			Chest pain	16	0
			Discomfort	2	0
			Pain	39	0
		Interactions	Drug interaction	4	0
			Adverse drug reaction	1	0

	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Drug ineffective	8	0
			Drug intolerance	1	0
			Therapeutic response decreased	1	0
	Tissue disorders NEC	Mass conditions NEC	Cyst	2	0
			Mass	1	0
	Bile duct disorders	Bile duct infections and inflammations	Biliary colic	14	0
			Cholangitis	1	0
		Obstructive bile duct disorders (excl neoplasms)	Bile duct stone	1	0
	Gallbladder disorders	Cholecystitis and cholelithiasis	Cholecystitis	12	0
			Cholecystitis acute	4	0
			Cholelithiasis	39	0
		Gallbladder disorders NEC	Gallbladder disorder	3	0
			Gallbladder rupture	1	0
		Cholestasis	Jaundice	7	0

Hepatobiliary disorders	Hepatic and hepatobiliary disorders	and jaundice	Ocular icterus	1	0
		Hepatic and hepatobiliary disorders NEC	Biloma	1	0
			Liver disorder	1	0
		Hepatic failure and associated disorders	Acute hepatic failure	1	0
			Hepatic failure	1	0
		Hepatocellular damage and hepatitis NEC	Autoimmune hepatitis	1	0
			Drug-induced liver injury	1	0
			Hepatitis	3	0
			Liver injury	7	0
			Metabolic dysfunction-associated liver disease	1	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	16	0
			Type I hypersensitivity	1	0
		Allergies to foods, food additives, drugs and other	Drug hypersensitivity	6	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	7	0

	Bacterial infectious disorders	Bacterial infections NEC	Bacterial food poisoning	1	0
			Cellulitis	5	0
		Staphylococcal infections	Furuncle	1	0
	Fungal infectious disorders	Candida infections	Oral candidiasis	1	0
		Abdominal and gastrointestinal infections	Appendicitis	9	0
			Appendicitis perforated	2	0
			Diverticulitis	4	0
			Gastroenteritis	4	0
			Peritonitis	1	0
		Dental and oral soft tissue infections	Gingivitis	1	0
		Eye and eyelid infections	Conjunctivitis	1	0
		Female reproductive tract infections	Vulvitis	1	0
		Infections NEC	Localised infection	1	0
			Omphalitis	1	0

Infections and infestations	Infections - pathogen unspecified		Post procedural infection	1	0
		Lower respiratory tract and lung infections	Pneumonia	2	1
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	4	0
			Septic shock	1	0
			Urosepsis	2	0
		Skin structures and soft tissue infections	Rash pustular	1	0
			Skin infection	1	0
		Upper respiratory tract infections	Laryngitis	1	0
			Nasopharyngitis	3	0
			Sinusitis	1	0
		Urinary tract infections	Cystitis	2	0
			Emphysematous pyelonephritis	1	0
			Kidney infection	1	0
			Pyelonephritis	1	0

			Urinary tract infection	8	0
	Viral infectious disorders	Coronavirus infections	COVID-19	4	0
		Herpes viral infections	Herpes zoster	4	0
			Oral herpes	1	0
		Influenza viral infections	Influenza	7	0
		Viral infections NEC	Gastroenteritis viral	3	0
			Viral infection	3	0
	Bone and joint injuries	Limb fractures and dislocations	Hand fracture	1	0
	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Maternal exposure during pregnancy	6	0
		Poisoning and toxicity	Toxicity to various agents	1	0
	Injuries by physical agents	Radiation injuries	Sunburn	1	0
		Thermal burns	Thermal burn	1	0
		Abdominal and gastrointestinal injuries NEC	Gallbladder injury	1	0
		Muscle, tendon and ligament	Muscle rupture	1	0

Injury, poisoning and procedural complications	Injuries NEC	and ligament injuries	Tendon rupture	1	0
		Non-site specific injuries NEC	Animal bite	1	0
			Fall	1	0
		Skin injuries NEC	Contusion	12	0
			Scar	1	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	39	0
			Prescription drug used without a prescription	1	0
			Wrong dose	1	0
			Wrong technique in product usage process	4	0
		Product administration errors and issues	Accidental underdose	10	0
			Expired product administered	4	0
			Extra dose administered	9	0
			Inappropriate schedule of product administration	1	0
			Incorrect dose administered	21	0

			Product dose omission issue	20	0
		Product prescribing errors and issues	Product prescribing error	1	0
			Product prescribing issue	2	0
	Off label uses and intentional product misuses/use issues	Intentional product misuses	Intentional product misuse	1	0
		Intentional product use issues	Intentional dose omission	1	0
		Off label uses	Off label use	14	0
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	3	0
		Underdoses NEC	Underdose	1	0
	Procedural related injuries and complications NEC	Neurological and psychiatric procedural complications	Procedural dizziness	1	0
		Non-site specific procedural complications	Injection related reaction	1	0
	Cardiac and vascular investigations (excl enzyme tests)	Heart rate and pulse investigations	Heart rate	9	0
			Heart rate abnormal	2	0
			Heart rate decreased	2	0
			Heart rate increased	19	0

		Maximum heart rate increased	1	0
	Vascular tests NEC (incl blood pressure)	Blood pressure decreased	2	0
		Blood pressure increased	2	0
Cytogenetic investigations and genetic analyses	Cell marker analyses	Human epidermal growth factor receptor increased	1	0
	Gene analyses	EGFR status assay	1	0
Endocrine investigations (incl sex hormones)	Adrenal cortex tests	Cortisol increased	1	0
	Reproductive hormone analyses	Blood testosterone increased	1	0
Gastrointestinal investigations	Digestive enzymes	Amylase	1	0
		Amylase increased	2	0
		Lipase increased	2	0
		Pancreatic enzymes	2	0
Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	International normalised ratio abnormal	1	0
		International normalised ratio decreased	1	0
	Platelet analyses	Platelet count decreased	1	0

Investigations	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	3	0
			Blood bilirubin increased	1	0
			Hepatic enzyme abnormal	2	0
			Hepatic enzyme increased	2	0
			Liver function test abnormal	8	0
			Liver function test increased	5	0
		Hepatobiliary imaging procedures	Liver scan	1	0
	Immunology and allergy investigations	Immune response protein analyses NEC	Interleukin level increased	1	0
	Investigations, imaging and histopathology procedures NEC	Investigations NEC	Blood test	1	0
			Blood test abnormal	1	0
	Lipid analyses	Cholesterol analyses	Blood cholesterol increased	1	0
		Blood gas and acid base analyses	Blood lactic acid increased	1	0
			Oxygen saturation decreased	1	0
			Blood glucose abnormal	3	0

Metabolic, nutritional and blood gas investigations	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose decreased	11	0
		Blood glucose fluctuation	2	0
		Blood glucose increased	5	0
		Glycosylated haemoglobin abnormal	1	0
		Glycosylated haemoglobin decreased	3	0
		Glycosylated haemoglobin increased	4	0
	Haem metabolism analyses	Blood methaemoglobin	1	0
	Metabolism tests NEC	Blood ketone body	5	0
	Vitamin analyses	Vitamin B12 decreased	1	0
Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature fluctuation	2	0
		Menstruation normal	1	0
		Weight decreased	9	0
		Weight increased	19	0
		C-reactive protein	1	0

	Protein and chemistry analyses NEC	Protein analyses NEC	Globulins increased	1	0
			Protein total increased	1	0
	Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine abnormal	1	0
			Blood creatinine increased	2	0
			Glomerular filtration rate abnormal	1	0
			Glomerular filtration rate decreased	3	0
		Urinalysis NEC	Blood urine present	2	0
			Nitrite urine present	1	0
		Urinary tract function analyses NEC	Urine output decreased	3	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood iron decreased	2	0
			Blood magnesium decreased	1	0
			Blood phosphorus decreased	1	0
		Water and electrolyte analyses NEC	Blood electrolytes abnormal	1	0
			Ketoacidosis	3	0

Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Ketosis	3	0
		Lactic acidosis	1	0
		Metabolic acidosis	1	0
		Starvation ketoacidosis	4	0
Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	26	0
		Food craving	5	0
		Hypophagia	2	0
		Increased appetite	6	0
	General nutritional disorders NEC	Abnormal loss of weight	1	0
		Abnormal weight gain	1	0
		Feeding disorder	9	0
		Malnutrition	2	0
Bone, calcium, magnesium and phosphorus metabolism disorders	Calcium metabolism disorders	Hypercalcaemia	1	0
	Phosphorus metabolism disorders	Hypophosphataemia	2	0

Metabolism  
and nutrition  
disorders

Diabetic complications	Diabetic complications NEC	Diabetic ketoacidosis	3	0
		Diabetic ketosis	1	0
		Euglycaemic diabetic ketoacidosis	3	0
Electrolyte and fluid balance conditions	Electrolyte imbalance NEC	Electrolyte imbalance	2	0
	Fluid intake decreased	Fluid intake reduced	1	0
	Fluid intake increased	Polydipsia	2	0
	Potassium imbalance	Hyperkalaemia	1	0
		Hypokalaemia	7	0
	Sodium imbalance	Hyponatraemia	1	0
	Total fluid volume decreased	Dehydration	31	0
	Total fluid volume increased	Fluid retention	2	0
Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar)	Food intolerance	1	0
	Sugar intolerance (excl glucose intolerance)	Lactose intolerance	1	0
	Diabetes mellitus (incl subtypes)	Diabetes mellitus inadequate control	2	0

	Glucose metabolism disorders (incl diabetes mellitus)	Hyperglycaemic conditions NEC	Hyperglycaemia	1	0
		Hypoglycaemic conditions NEC	Hypoglycaemia	34	0
			Hypoglycaemia unawareness	1	0
	Iron and trace metal metabolism disorders	Iron deficiencies	Iron deficiency	1	0
	Purine and pyrimidine metabolism disorders	Disorders of purine metabolism	Gout	5	0
	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Bone pain	3	0
			Pain in jaw	3	0
			Spinal pain	1	0
	Connective tissue disorders (excl congenital)	Lupus erythematosus (incl subtypes)	Systemic lupus erythematosus	1	0
	Joint disorders	Arthropathies NEC	Arthritis	2	0
		Joint related signs and symptoms	Arthralgia	27	0
			Joint stiffness	2	0
			Joint swelling	2	0
		Osteoarthropathies	Spinal osteoarthritis	1	0

Musculoskeletal and connective tissue disorders	Muscle disorders	Muscle pains	Fibromyalgia	2	0
			Myalgia	41	0
		Muscle related signs and symptoms NEC	Muscle atrophy	3	0
			Muscle fatigue	2	0
			Muscle mass	1	0
			Muscle spasms	6	0
			Muscle tightness	1	0
			Muscle twitching	2	0
		Muscle tone abnormalities	Trismus	3	0
		Muscle weakness conditions	Muscular weakness	3	0
		Myopathies	Myopathy	1	0
			Rhabdomyolysis	1	0
	Musculoskeletal and connective tissue conditions NEC		Mastication disorder	1	0
			Mobility decreased	1	0

	Musculoskeletal and connective tissue disorders NEC		Musculoskeletal stiffness	2	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	25	0
			Flank pain	1	0
			Limb discomfort	1	0
			Musculoskeletal chest pain	7	0
			Musculoskeletal discomfort	3	0
			Musculoskeletal pain	1	0
			Neck pain	18	0
			Pain in extremity	25	0
		Soft tissue disorders NEC	Neck mass	1	0
	Tendon, ligament and cartilage disorders	Tendon disorders	Tendonitis	1	0
Neoplasms	Breast neoplasms malignant and unspecified (incl nipple)	Breast and nipple neoplasms malignant	Breast cancer	3	0
	Cutaneous neoplasms benign	Skin neoplasms benign	Seborrhoeic keratosis	1	0
	Endocrine neoplasms malignant and unspecified	Endocrine neoplasms malignant and unspecified NEC	Thyroid neoplasm	1	0

benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal neoplasms malignant and unspecified	Gastrointestinal neoplasms malignant NEC	Gastrointestinal carcinoma	1	0
	Hepatobiliary neoplasms malignant and unspecified	Bile duct neoplasms malignant	Cholangiocarcinoma	2	0
	Miscellaneous and site unspecified neoplasms malignant and	Neoplasms malignant site unspecified NEC	Neoplasm malignant	1	0
	Skin neoplasms malignant and unspecified	Skin melanomas (excl ocular)	Malignant melanoma	1	0
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebrovascular accident	4	0
			Haemorrhage intracranial	1	0
			Ruptured cerebral aneurysm	1	0
		Transient cerebrovascular events	Transient ischaemic attack	2	0
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	1	0
		Olfactory nerve disorders	Parosmia	2	0
	Headaches	Headaches NEC	Cluster headache	2	0
			Headache	1,043	0
			Sinus headache	1	0
			Tension headache	1	0

Headaches	Migraine headaches	Migraine	16	0
		Migraine without aura	1	0
		Ophthalmic migraine	1	0
		Retinal migraine	1	0
Mental impairment disorders	Memory loss (excl dementia)	Amnesia	3	0
Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Psychomotor hyperactivity	1	0
	Paralysis and paresis (excl cranial nerve)	Paralysis	1	0
	Parkinson's disease and parkinsonism	Freezing phenomenon	1	0
	Tremor (excl congenital)	Tremor	12	0
	Coordination and balance disturbances	Balance disorder	1	0
		Nystagmus	1	0
	Cortical dysfunction NEC	Aphasia	1	0
	Disturbances in consciousness	Lethargy	21	0
		Loss of consciousness	2	0

Nervous  
system  
disorders

Neurological  
disorders NEC

consciousness NEC	Somnolence	8	0
	Syncope	8	0
Neurological signs and symptoms NEC	Brain fog	3	0
	Dizziness	107	0
	Dizziness postural	4	0
	Head discomfort	2	0
	Myoclonus	1	0
	Presyncope	1	0
Paraesthesias and dysaesthesias	Burning sensation	5	0
	Hyperaesthesia	3	0
	Hypoaesthesia	9	0
	Paraesthesia	23	0
	Ageusia	2	0
	Allodynia	19	0

		Sensory abnormalities NEC	Aura	1	0
			Dysgeusia	14	0
			Neuralgia	3	0
			Restless legs syndrome	5	0
			Taste disorder	5	0
		Speech and language abnormalities	Dysarthria	1	0
			Speech disorder	2	0
	Peripheral neuropathies	Mononeuropathies	Peroneal nerve palsy	1	0
		Peripheral neuropathies NEC	Neuritis	1	0
			Neuropathy peripheral	4	0
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Seizure	8	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	2	0
		Sleep disturbances NEC	Sleep deficit	1	0
	Abortions and stillbirth	Abortions spontaneous	Abortion spontaneous	2	0

Pregnancy, puerperium and perinatal conditions	Maternal complications of pregnancy	Maternal complications of pregnancy NEC	Biochemical pregnancy	1	0
			Morning sickness	2	0
	Pregnancy, labour, delivery and postpartum conditions	Normal pregnancy, labour and delivery	Pregnancy	3	0
		Unintended pregnancies	Unwanted pregnancy	1	0
Product issues	Device issues	Device physical property and chemical issues	Device defective	1	0
	Adjustment disorders (incl subtypes)	Adjustment disorders	Adjustment disorder with depressed mood	1	0
	Anxiety disorders and symptoms	Anxiety disorders NEC	Anxiety disorder	1	0
		Anxiety symptoms	Agitation	2	0
			Anxiety	58	0
			Nervousness	4	0
			Stress	2	0
		Panic attacks and disorders	Panic attack	21	0
			Panic disorder	3	0
			Panic reaction	2	0

Changes in physical activity	Increased physical activity levels	Restlessness	2	0
Cognitive and attention disorders and disturbances	Cognitive and attention disorders and disturbances NEC	Mental fatigue	2	0
Communication disorders and disturbances	Communication disorders	Communication disorder	1	0
Deliria (incl confusion)	Confusion and disorientation	Confusional state	6	0
		Disorientation	1	0
	Deliria	Delirium	1	0
Depressed mood disorders and disturbances	Depressive disorders	Depression	20	0
		Depression suicidal	1	0
		Major depression	1	0
	Mood alterations with depressive symptoms	Anhedonia	3	0
		Decreased interest	1	0
		Depressed mood	111	0
		Negative thoughts	1	0
	Perception disturbances NEC	Flashback	1	0

Psychiatric disorders

Disturbances in thinking and perception	Thinking disturbances	Intrusive thoughts	1	0
		Tachyphrenia	2	0
Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Anger	2	0
		Emotional distress	1	0
		Irritability	5	0
		Mood altered	2	0
	Fluctuating mood symptoms	Mood swings	2	0
Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Paranoia	1	0
	Personality disorders NEC	Personality disorder	1	0
Psychiatric disorders NEC	Mental disorders due to a general medical condition NEC	Neuropsychiatric syndrome	1	0
	Mental disorders NEC	Mental disorder	2	0
	Substance related and addictive disorders	Alcoholism	1	0
Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Acute psychosis	1	0
Sexual	Orgasmic disorders and disturbances	Female orgasmic disorder	1	0

	dysfunctions, disturbances and gender identity disorders	Sexual desire disorders	Libido decreased	1	0
			Loss of libido	1	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	34	0
		Dyssomnias	Poor quality sleep	7	0
		Parasomnias	Abnormal dreams	8	0
			Nightmare	8	0
		Sleep disorders NEC	Sleep disorder	5	0
			Sleep disorder due to a general medical condition	2	0
			Sleep disorder due to general medical condition, insomnia type	5	0
	Somatic symptom and related disorders	Somatic symptom disorders	Somatic symptom disorder	1	0
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour	Completed suicide	1	1
			Suicidal ideation	10	0
			Suicide attempt	2	0
			Acute kidney injury	10	0

Renal and urinary disorders

Renal disorders (excl nephropathies)	Renal failure and impairment	Anuria	1	0
		Renal failure	1	0
		Renal impairment	3	0
	Bladder and urethral symptoms	Bladder pain	1	0
		Dysuria	2	0
		Incontinence	2	0
		Micturition urgency	2	0
		Pollakiuria	3	0
		Urinary hesitation	1	0
		Urinary incontinence	1	0
		Urinary retention	1	0
		Urinary straining	1	0
	Urinary abnormalities	Chromaturia	4	0
		Haematuria	4	0
Urinary tract signs and symptoms	Bladder and urethral symptoms	Bladder pain	1	0
		Dysuria	2	0
		Incontinence	2	0
		Micturition urgency	2	0
		Pollakiuria	3	0
		Urinary hesitation	1	0
		Urinary incontinence	1	0
		Urinary retention	1	0
		Urinary straining	1	0
	Urinary abnormalities	Chromaturia	4	0
		Haematuria	4	0

		Urinary tract signs and symptoms NEC	Haemorrhage urinary tract	1	0
			Polyuria	3	0
			Renal pain	5	0
	Urolithiases	Renal lithiasis	Nephrolithiasis	6	1
	Breast disorders	Breast signs and symptoms	Breast tenderness	1	0
		Lactation disorders	Lactation disorder	1	0
	Menopause related conditions	Menopausal effects NEC	Menopausal symptoms	1	0
		Menopausal effects on the genitourinary tract	Postmenopausal haemorrhage	3	0
	Menstrual cycle and uterine	Menstruation and uterine bleeding NEC	Abnormal menstrual clots	1	0
			Dysmenorrhoea	9	0
			Intermenstrual bleeding	16	0
			Menstrual clots	1	0
			Menstrual disorder	19	0
			Menstruation irregular	19	0

Reproductive system and breast disorders	bleeding disorders		Withdrawal bleed	1	0
		Menstruation with decreased bleeding	Amenorrhoea	3	0
			Menstruation delayed	15	0
			Oligomenorrhoea	1	0
		Menstruation with increased bleeding	Heavy menstrual bleeding	28	0
			Polymenorrhoea	4	0
	Ovarian and fallopian tube disorders	Ovarian and fallopian tube cysts and neoplasms	Ovarian cyst ruptured	1	0
			Polycystic ovaries	1	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Pruritus genital	1	0
	Sexual function and fertility disorders	Erection and ejaculation conditions and disorders	Erectile dysfunction	1	0
	Uterine, pelvic and broad ligament disorders	Pelvis and broad ligament disorders NEC	Pelvic haemorrhage	1	0
		Uterine tone disorders	Uterine spasm	1	0
	Vulvovaginal disorders (excl	Vulvovaginal disorders NEC	Vaginal haemorrhage	21	0
			Vulval haemorrhage	1	0

	infections and inflammations)	Vulvovaginal signs and symptoms	Vaginal lesion	1	0
			Vulvovaginal dryness	2	0
Respiratory, thoracic and	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	3	0
			Wheezing	2	0
	Lower respiratory tract disorders (excl obstruction and infection)	Lower respiratory tract inflammatory and	Diffuse alveolar damage	1	0
		Parenchymal lung disorders NEC	Acute interstitial pneumonitis	1	0
	Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	4	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	14	0
			Respiration abnormal	1	0
		Coughing and associated symptoms	Cough	7	0
		Lower respiratory tract signs and symptoms	Hiccups	1	0
			Aphonia	1	0
			Catarrh	1	0
			Dysphonia	9	0

mediastinal disorders	Respiratory tract signs and symptoms	Upper respiratory tract signs and symptoms	Oropharyngeal discomfort	1	0
			Oropharyngeal pain	7	0
			Rhinalgia	1	0
			Rhinorrhoea	1	0
			Throat irritation	2	0
			Upper-airway cough syndrome	1	0
	Thoracic disorders (excl lung and pleura)	Mediastinal disorders	Pneumomediastinum	1	0
	Upper respiratory tract disorders (excl infections)	Laryngeal and adjacent sites disorders NEC (excl infections and	Reflux laryngitis	3	0
		Nasal congestion and inflammations	Nasal congestion	2	0
		Nasal disorders NEC	Epistaxis	4	0
		Pharyngeal disorders (excl infections and neoplasms)	Oropharyngeal spasm	1	0
			Pharyngeal swelling	1	0
	Angioedema and urticaria	Angioedemas	Angioedema	6	0
		Urticariae	Idiopathic urticaria	1	0

	Urticaria	Urticaria	39	0
Cutaneous neoplasms benign	Skin cysts and polyps	Dermal cyst	1	0
	Bullous conditions	Blister	2	0
		Dermatitis bullous	1	0
		Dermatitis herpetiformis	1	0
	Dermal and epidermal conditions NEC	Dry skin	6	0
		Pain of skin	6	0
		Sensitive skin	9	0
		Skin burning sensation	1	0
		Skin discolouration	1	0
		Skin disorder	1	0
		Skin induration	1	0
		Skin lesion	1	0
		Skin reaction	7	0

Skin and subcutaneous tissue disorders	Epidermal and dermal conditions		Skin sensitisation	8	0
			Skin swelling	1	0
		Dermatitis and eczema	Dermatitis	1	0
			Dermatitis allergic	7	0
			Eczema	3	0
			Intertrigo	1	0
			Skin irritation	5	0
		Dermatitis ascribed to specific agent	Drug eruption	1	0
			Severe cutaneous adverse reaction	1	0
		Erythemas	Erythema	13	0
		Exfoliative conditions	Skin exfoliation	2	0
		Papulosquamous conditions	Lichen planus	1	0
		Photosensitivity and photodermatoses conditions	Photosensitivity reaction	1	0
		Pruritus NEC	Pruritus	48	0

		Psoriatic conditions	Psoriasis	1	0
	Rashes, eruptions and exanthems NEC		Rash	67	0
			Rash erythematous	18	0
			Rash macular	3	0
			Rash papular	2	0
			Rash pruritic	14	0
			Rash vesicular	2	0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	1	0
	Skin appendage conditions	Acnes	Acne	4	0
		Alopecias	Alopecia	64	0
		Apocrine and eccrine gland disorders	Cold sweat	3	0
			Hidradenitis	1	0
			Hyperhidrosis	26	0
			Miliaria	1	0

			Night sweats	1	0
		Pilar disorders NEC	Hair colour changes	1	0
			Hair growth abnormal	1	0
		Rosaceas	Rosacea	1	0
	Skin vascular abnormalities	Purpura and related conditions	Purpura	1	0
Social circumstances	Age related factors	Age related issues	Menopause	1	0
	Economic and housing issues	Economic circumstances	Low income	1	0
	Family issues	Family and partner issues	Anxious parent	1	0
	Lifestyle issues	Disability issues	Impaired work ability	1	0
		Tobacco use	Ex-tobacco user	1	0
			Non-tobacco user	1	0
	Endocrine gland therapeutic procedures	Hormonal therapeutic procedures NEC	Hormone replacement therapy	1	0
	Gastrointestinal therapeutic procedures	Large intestine therapeutic procedures	Appendicectomy	3	0
	Hepatobiliary therapeutic procedures	Biliary tract and gallbladder therapeutic procedures	Cholecystectomy	4	0

Surgical and medical procedures	Obstetric and gynaecological therapeutic procedures	Contraceptive methods female	Contraception	1	0
		Uterine therapeutic procedures	Myomectomy	1	0
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Hospitalisation	7	0
			Rest regimen	1	0
Vascular	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	5	0
			Raynaud's phenomenon	2	0
	Decreased and nonspecific blood pressure disorders and shock	Blood pressure disorders NEC	Blood pressure fluctuation	1	0
		Circulatory collapse and shock	Circulatory collapse	1	0
			Shock	2	0
		Vascular hypotensive disorders	Hypotension	13	0
			Orthostatic hypotension	3	0
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Thrombosis	1	0
		Peripheral embolism and thrombosis	Deep vein thrombosis	5	0
			Thrombophlebitis	1	0

disorders	Vascular disorders NEC	Non-site specific vascular disorders NEC	Vascular calcification	1	0
		Peripheral vascular disorders NEC	Cyanosis	2	0
			Flushing	2	0
			Hot flush	8	0
		Site specific vascular disorders NEC	Pallor	2	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	3	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	7	0
	Vascular infections and inflammations	Phlebitis NEC	Phlebitis	1	0
		Vasculitides NEC	Vasculitis	1	0
	Venous varices	Varicose veins NEC	Varicose vein	2	0
	Total reactions for drug			12,598	
	Total reports for drug			7,982	
	Total fatal outcome				12

