

Clostridium botulinum Drug Analysis Print.

All UK spontaneous suspected reports associated with Clostridium botulinum between 01/01/1998 up to and including 25/03/2025

Report run 26/03/2025

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total reports	Fatal
Blood and lymphatic system disorders	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Petechiae	1	0
	Haematological disorders NEC	Haematological disorders	Mast cell activation syndrome	1	0
			Methaemoglobin aemia	1	0
	Haematopoietic neoplasms (excl leukaemias and lymphomas)	Myeloproliferative disorders (excl leukaemias)	Polycythaemia vera	1	0
	Haemoglobinopathies	Thalassaemic disorders	Thalassaemia beta	1	0
	Haemolyses and related conditions	Anaemias haemolytic NEC	Haemolytic anaemia	1	0
		Haemolyses NEC	Jaundice	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	1	0
			Lymphadenopathy	10	0
			Lymphatic disorder	4	0
			Lymphatic obstruction	1	0
			Lymphoedema	1	0
		Spleen disorders	Splenomegaly	1	0
	Total			24	0
Cardiac disorders	Cardiac arrhythmias	Cardiac conduction disorders	Atrioventricular block	1	0
			Atrioventricular block first degree	1	0
		Rate and rhythm disorders NEC	Arrhythmia	5	0
			Postural orthostatic tachycardia syndrome	3	0
			Tachycardia	7	0
		Supraventricular arrhythmias	Atrial fibrillation	4	0
			Sinus bradycardia	1	0
		Ventricular	Cardiac arrest	3	1

		arrhythmias and cardiac arrest	Cardio-respiratory arrest	1	0
			Sudden death	2	2
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Acute cardiac event	1	0
		Cardiac signs and symptoms NEC	Cyanosis	3	0
			Dizziness	92	0
			Dizziness exertional	1	0
			Dizziness postural	4	0
			Palpitations	37	0
			Presyncope	7	0
			Syncope	19	0
		Dyspnoeas	Dyspnoea	73	0
			Dyspnoea exertional	2	0
	Coronary artery disorders	Ischaemic coronary artery disorders	Acute myocardial infarction	1	1
			Angina pectoris	1	0
			Chest discomfort	9	0
			Chest pain	14	0
			Myocardial infarction	3	0
	Heart failures	Heart failure signs and symptoms	Oedema peripheral	3	0
			Peripheral swelling	10	0
		Heart failures NEC	Cardiac failure	2	0
			Cardiopulmonary failure	1	0
		Left ventricular failures	Acute left ventricular failure	1	1
			Pulmonary oedema	1	0
	Myocardial disorders	Cardiomyopathies	Dilated cardiomyopathy	1	0
		Myocardial disorders NEC	Cardiomegaly	1	0
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	1	0
	Total			231	5
Congenital, familial and genetic disorders	Blood and lymphatic system disorders congenital	Haemoglobinopathies congenital	Thalassaemia beta	1	0
	Cytoplasmic disorders congenital	Genetic mitochondrial abnormalities NEC	Mitochondrial DNA mutation	1	0

	Respiratory disorders congenital	Laryngeal and tracheal disorders congenital	Laryngomalacia	1	0
	Total			3	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Cholesteatoma	1	0
			Ear congestion	3	0
			Ear discomfort	4	0
			Ear disorder	1	0
			Ear infection	3	0
			Ear pain	8	0
			Ear swelling	1	0
	External ear disorders (excl congenital)	External ear infections and inflammations	External ear inflammation	1	0
	Hearing disorders	Hearing losses	Deafness	4	0
			Deafness neurosensory	1	0
			Deafness unilateral	1	0
			Hypoacusis	3	0
		Hyperacusis	Hyperacusis	3	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Inner ear disorder	1	0
			Meniere's disease	1	0
		Inner ear infections and inflammations	Labyrinthitis	1	0
		Inner ear signs and symptoms	Motion sickness	1	0
			Tinnitus	17	0
			Vertigo	19	0
			Vestibular migraine	2	0
	Middle ear disorders (excl congenital)	Mastoid disorders	Mastoiditis	1	0
		Middle ear infections and inflammations	Otitis media	1	0
		Tympanic membrane disorders (excl infections)	Tympanic membrane disorder	1	0
			Tympanic membrane perforation	1	0
	Total			57	0
Endocrine disorders	Endocrine disorders of gonadal function	Endocrine abnormalities of gonadal function NEC	Androgenetic alopecia	1	0
		Female gonadal function disorders	Amenorrhoea	1	0

	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Type 1 diabetes mellitus	1	0
	Hypothalamus and pituitary gland disorders	Hypothalamic and pituitary disorders NEC	Temperature regulation disorder	1	0
	Thyroid gland disorders	Acute and chronic thyroiditis	Thyroiditis	1	0
	Total			5	0
Eye disorders	Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	1	0
		Conjunctival structural change, deposit and degeneration	Conjunctival disorder	2	0
		Corneal structural change, deposit and	Corneal degeneration	2	0
			Corneal perforation	2	0
		Lid, lash and lacrimal structural disorders	Brow ptosis	25	0
			Eyelid skin dryness	1	0
			Eyelid thickening	2	0
			Lagophthalmos	2	0
			Madarosis	2	0
	Eye disorders NEC	Corneal disorders NEC	Keratoneuralgia	1	0
		Lacrimation disorders	Dry eye	35	0
			Lacrimation decreased	2	0
			Lacrimation increased	14	0
		Ocular disorders NEC	Dark circles under eyes	4	0
			Eye disorder	11	0
			Eye oedema	4	0
			Eye pain	26	0
			Eye swelling	29	0
			Eyelid disorder	9	0
			Eyelid pain	1	0
			Eyelids pruritus	4	0
			Ocular discomfort	6	0
			Periorbital discomfort	1	0
			Periorbital oedema	3	0
			Periorbital swelling	35	0

Glaucoma and ocular hypertension	Glaucomas (excl congenital)	Glaucoma	2	0
Ocular haemorrhages and vascular disorders NEC	Conjunctival and corneal bleeding and vascular disorders	Conjunctival haemorrhage	2	0
Ocular infections, irritations and inflammations	Conjunctival infections, irritations and inflammations	Conjunctival hyperaemia	1	0
		Conjunctivitis	1	0
		Seasonal allergy	1	0
	Corneal infections, oedemas and	Keratitis	2	0
		Ulcerative keratitis	2	0
	Iris and uveal tract infections,	Iridocyclitis	1	0
		Uveitis	1	0
	Lid, lash and lacrimal infections, irritations and inflammations	Blepharitis	3	0
		Eczema eyelids	1	0
		Erythema of eyelid	3	0
		Eyelid irritation	2	0
		Eyelid oedema	2	0
		Hordeolum	1	0
		Swelling of eyelid	12	0
	Ocular infections, inflammations and associated manifestations	Eye discharge	1	0
		Eye inflammation	1	0
		Eye irritation	5	0
		Eye pruritus	8	0
		Ocular hyperaemia	7	0
	Optic nerve infections and inflammations	Optic neuritis	1	0
	Orbital infections, inflammations and irritations	Cellulitis orbital	3	0
Ocular injuries	Ocular injuries NEC	Eye contusion	2	0
		Eye injury	2	0
		Open globe injury	1	0
	Optic pathway injuries	Optic nerve injury	1	0
Ocular neuromuscular disorders	Eyelid movement	Blepharospasm	10	0
		Eyelid ptosis	84	0
	Ocular nerve and muscle disorders	Eye movement disorder	1	0
		Heterophoria	1	0
		Ocular myasthenia	1	0

		Oculogyric crisis	1	0
		Ophthalmoplegia	2	0
		Strabismus	12	0
		Vlth nerve paralysis	1	0
	Pupil disorders	Mydriasis	2	0
Ocular sensory symptoms NEC	Ocular sensation disorders	Abnormal sensation in eye	4	0
		Asthenopia	10	0
		Eyelid sensory disorder	2	0
		Foreign body sensation in eyes	4	0
		Photophobia	9	0
Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit	Vitreous detachment	1	0
		Vitreous floaters	6	0
	Orbital structural change, deposit and	Lid sulcus deepened	2	0
		Orbital swelling	1	0
Retina, choroid and vitreous haemorrhages and vascular disorders	Choroid and vitreous haemorrhages and vascular disorders	Vitreous haemorrhage	1	0
	Retinal bleeding and vascular disorders (excl retinopathy)	Retinal vein occlusion	2	0
	Retinopathies NEC	Central serous chorioretinopathy	1	0
Vision disorders	Refractive and accommodative disorders	Myopia	1	0
	Visual disorders NEC	Diplopia	37	0
		Photopsia	2	0
		Vision blurred	67	0
		Visual snow syndrome	1	0
	Visual field disorders	Visual field defect	1	0
	Visual impairment and blindness (excl colour blindness)	Blindness	3	0
		Blindness transient	2	0
		Visual impairment	22	0
Total			356	0

Gastrointestinal disorders	Dental and gingival conditions	Dental and periodontal infections and inflammations	Tooth infection	1	0
		Dental developmental disorders and anomalies	Tooth impacted	1	0
		Dental disorders NEC	Tooth disorder	2	0
		Dental pain and sensation disorders	Hyperaesthesia teeth	1	0
			Hypoaesthesia teeth	1	0
			Toothache	2	0
		Gingival disorders, signs	Gingival blister	1	0
			Gingival pain	2	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	6	0
	Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Oesophageal intramural haematoma	1	0
		Non-site specific gastrointestinal haemorrhages	Gastrointestinal haemorrhage	1	0
			Haematochezia	1	0
	Gastrointestinal infections	Gastric and gastroenteric infections	Gastroenteritis viral	1	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Crohn's disease	1	0
			Inflammatory bowel disease	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	27	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	6	0
			Gastrooesophageal reflux disease	4	0
			Impaired gastric emptying	2	0
			Oesophageal hypomotility	1	0
		Gastrointestinal dyskinetic disorders	Bowel movement irregularity	1	0
		Gastrointestinal spastic and hypermotility disorders	Defaecation urgency	1	0
			Frequent bowel movements	1	0
		Non-mechanical ileus	Ileus paralytic	1	0
	Gastrointestinal signs and symptoms	Abdominal findings abnormal	Abdominal mass	1	0
		Dyspeptic signs	Dyspepsia	1	0

and symptoms	Eructation	1	0
Faecal abnormalities NEC	Abnormal faeces	2	0
Flatulence, bloating and distension	Abdominal distension	3	0
Gastrointestinal and abdominal pains (excl oral	Abdominal pain	6	0
	Abdominal pain upper	8	0
Gastrointestinal signs and symptoms NEC	Abdominal discomfort	4	0
	Anal incontinence	5	0
	Bruxism	1	0
	Dysphagia	98	0
	Incontinence	2	0
	Mastication disorder	3	0
	Pelvic pain	1	0
	Portal venous gas	1	0
Nausea and vomiting symptoms	Meniere's disease	1	0
	Nausea	72	0
	Procedural nausea	1	0
	Vomiting	26	0
Gastrointestinal vascular occlusion and infarction	Intestinal ischaemia	1	0
Malabsorption syndromes	Gluten sensitivity	1	0
Malignant miscellaneous gastrointestinal neoplasms	Gastrointestinal carcinoma	1	0
Pancreatic neoplasms	Pancreatic carcinoma	1	0
Oral soft tissue disorders NEC	Cheilitis	1	0
	Lip disorder	1	0
	Oral disorder	1	0
	Palatal disorder	1	0
Oral soft tissue infections	Oral candidiasis	5	0
	Oral herpes	1	0
	Oral infection	1	0
	Pharyngitis	2	0
Oral soft tissue signs and symptoms	Hypoaesthesia oral	8	0
	Lip discolouration	1	0
	Lip pain	1	0
	Oral discomfort	2	0
	Oral pain	3	0

			Oropharyngeal pain	12	0
			Paraesthesia oral	5	0
		Oral soft tissue swelling and	Lip swelling	9	0
			Mouth swelling	1	0
		Stomatitis and ulceration	Mouth ulceration	1	0
	Peritoneal and retroperitoneal conditions	Peritoneal and retroperitoneal disorders	Chemical peritonitis	1	0
	Salivary gland conditions	Oral dryness and saliva	Dry mouth	28	0
			Dry throat	5	0
		Salivary gland infections and inflammations	Sialoadenitis	1	0
	Tongue conditions	Taste disorders	Ageusia	1	0
			Dysgeusia	7	0
			Taste disorder	3	0
		Tongue disorders	Tongue disorder	1	0
			Tongue geographic	1	0
		Tongue signs and symptoms	Swollen tongue	11	0
			Tongue paralysis	2	0
			Tongue pruritus	1	0
	Total			282	0
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site acne	1	0
			Administration site infection	1	0
			Administration site necrosis	1	0
			Administration site rash	1	0
			Administration site swelling	1	0
			Puncture site haemorrhage	1	0
		Application and instillation site reactions	Application site erythema	1	0
			Application site swelling	1	0
		Application site reactions	Application site erythema	1	0
			Application site swelling	1	0
		Implant and catheter site reactions	Catheter site haemorrhage	1	0
		Injection site reactions	Injection site abscess	1	0
			Injection site alopecia	1	0

Injection site bruising	21	0
Injection site discolouration	2	0
Injection site discomfort	5	0
Injection site dryness	1	0
Injection site erythema	16	0
Injection site fibrosis	1	0
Injection site granuloma	2	0
Injection site haematoma	1	0
Injection site haemorrhage	2	0
Injection site hypersensitivity	9	0
Injection site hypoaesthesia	4	0
Injection site indentation	5	0
Injection site induration	4	0
Injection site infection	3	0
Injection site injury	1	0
Injection site mass	40	0
Injection site movement impairment	1	0
Injection site muscle atrophy	1	0
Injection site muscle weakness	1	0
Injection site nerve damage	1	0
Injection site nodule	5	0
Injection site pain	79	0
Injection site pallor	1	0
Injection site papule	2	0
Injection site paraesthesia	3	0
Injection site pruritus	12	0

		Injection site pustule	1	0
		Injection site rash	8	0
		Injection site reaction	6	0
		Injection site scar	1	0
		Injection site swelling	40	0
		Injection site ulcer	1	0
		Injection site vesicles	1	0
Body temperature conditions	Body temperature altered	Temperature regulation disorder	1	0
	Febrile disorders	Pyrexia	27	0
Fatal outcomes	Death and sudden death	Death	2	2
		Sudden death	2	2
General system disorders NEC	Adverse effect absent	No adverse event	1	0
	Asthenic conditions	Asthenia	63	0
		Autonomic nervous system imbalance	1	0
		Chronic fatigue syndrome	1	0
		Decreased activity	1	0
		Fatigue	76	0
		Lethargy	8	0
		Malaise	64	0
	Feelings and sensations NEC	Burning sensation	23	0
		Chills	6	0
		Decreased appetite	11	0
		Feeling abnormal	17	0
		Feeling cold	4	0
		Feeling drunk	1	0
		Feeling hot	6	0
		Feeling of body temperature change	4	0
		Hangover	2	0
		Peripheral coldness	2	0
		Sensation of foreign body	1	0
		Temperature intolerance	2	0
		Thirst	2	0

Gait disturbances	Gait disturbance	7	0
	Gait inability	1	0
General signs and symptoms NEC	Balance disorder	9	0
	Cold sweat	1	0
	Condition aggravated	22	0
	Crepitations	1	0
	Dark circles under eyes	4	0
	Deformity	2	0
	Disease progression	2	0
	Dysstasia	5	0
	Flushing	6	0
	General physical health deterioration	1	0
	General symptom	2	0
	Hot flush	2	0
	Hyperhidrosis	14	0
	Illness	12	0
	Induration	1	0
	Influenza like illness	55	0
	Irritability	2	0
	Local reaction	2	0
	Mobility decreased	5	0
	Multiple organ dysfunction syndrome	1	0
	Night sweats	4	0
	Organ failure	1	0
	Pallor	6	0
	Peripheral swelling	10	0
	Purulent discharge	1	0
	Secretion discharge	1	0
	Swelling	35	0
	Swelling face	51	0
	Symptom recurrence	1	0
	Unevaluable event	4	0
Inflammations	Granuloma	1	0
	Inflammation	10	0
	Papillitis	1	0
Mucosal findings abnormal	Drug eruption	2	0
	Mucosal inflammation	1	0

Oedema NEC	Allergic oedema	1	0
	Face oedema	10	0
	Oedema	11	0
	Oedema peripheral	3	0
Pain and discomfort NEC	Chest discomfort	9	0
	Chest pain	14	0
	Discomfort	9	0
	Facial discomfort	8	0
	Facial pain	13	0
	Flank pain	1	0
	Inflammatory pain	1	0
	Pain	58	0
	Spinal pain	1	0
	Tenderness	5	0
Interactions	Drug interaction	3	0
Therapeutic and nontherapeutic responses	Adverse drug reaction	13	0
	Adverse event	7	0
	Adverse reaction	2	0
	Drug effect less than expected	2	0
	Drug effective for unapproved indication	4	0
	Drug ineffective	60	0
	Drug ineffective for unapproved indication	5	0
	Drug intolerance	1	0
	Drug resistance	4	0
	Drug tolerance	1	0
	Loss of therapeutic response	1	0
	Therapeutic product effect decreased	3	0
	Therapeutic product effect delayed	1	0
	Therapeutic product effect incomplete	6	0
	Therapeutic product effect increased	1	0
	Therapeutic product ineffective	1	0

			Therapeutic response decreased	9	0
			Therapeutic response increased	1	0
			Therapeutic response shortened	17	0
			Therapeutic response unexpected	3	0
			Treatment noncompliance	1	0
	Tissue disorders NEC	Withdrawal and rebound effects	Electric shock sensation	7	0
		Healing abnormal NEC	Impaired healing	1	0
		Mass conditions NEC	Cyst	1	0
			Mass	5	0
			Nodule	7	0
		Necrosis NEC	Fat necrosis	1	0
		Trophic disorders	Atrophy	2	0
			Calcinosis	1	0
	Dysplasia		2	0	
	Total			705	4
Hepatobiliary disorders	Bile duct disorders	Bile duct infections and inflammations	Biliary colic	1	0
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	1	0
		Hepatic viral infections	Acute hepatitis B	1	0
		Hepatobiliary signs and symptoms	Hepatic pain	1	0
		Hepatocellular damage and hepatitis NEC	Hepatitis chronic active	2	0
			Hepatotoxicity	1	0
Total			5	0	
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergic oedema	1	0
			Asthma	3	0
			Dermatitis allergic	1	0
			Hypersensitivity	38	0
			Injection site hypersensitivity	9	0
			Multiple allergies	2	0
			Panniculitis	1	0
			Serum sickness	1	0
			Skin reaction	1	0
			Type I hypersensitivity	1	0

	Type IV hypersensitivity reaction	3	0
Allergies to foods, food additives, drugs and other chemicals	Dermatitis contact	1	0
	Drug eruption	2	0
	Drug hypersensitivity	14	0
	Gluten sensitivity	1	0
Anaphylactic and anaphylactoid responses	Anaphylactic reaction	9	0
	Anaphylactic shock	1	0
Angioedemas	Angioedema	6	0
	Circumoral swelling	1	0
	Eyelid oedema	2	0
	Face oedema	10	0
	Lip swelling	9	0
	Mouth swelling	1	0
	Orbital swelling	1	0
	Periorbital oedema	3	0
	Periorbital swelling	35	0
	Swelling face	51	0
	Swelling of eyelid	12	0
	Swollen tongue	11	0
Atopic disorders	Seasonal allergy	1	0
Urticarias	Urticaria	20	0
	Urticaria cholinergic	1	0
Autoimmune disorders NEC	Autoimmune disorder	1	0
Endocrine autoimmune disorders	Type 1 diabetes mellitus	1	0
Lupus erythematosus and associated conditions	Systemic lupus erythematosus	1	0
Muscular autoimmune disorders	Myasthenia gravis	1	0
	Ocular myasthenia	1	0
	Polymyalgia rheumatica	1	0
Nervous system autoimmune disorders	Guillain-Barre syndrome	5	0
	Myelitis transverse	2	0

			Stiff leg syndrome	1	0
			Rheumatoid arthritis and associated conditions	1	0
			Skin autoimmune disorders NEC	1	0
	Immune disorders NEC	Acute and chronic sarcoidosis	Sarcoidosis	1	0
		Immune and associated conditions NEC	Acute respiratory distress syndrome	1	0
			Crohn's disease	1	0
			Cystitis interstitial	1	0
			Inflammation	10	0
			Mast cell activation syndrome	1	0
			Optic neuritis	1	0
			Psoriasis	1	0
			Ulcerative keratitis	2	0
			Uveitis	1	0
		Vasculitides	Granulomatosis with polyangiitis	1	0
		Total		239	0
Infections and infestations	Ancillary infectious topics	Inflammatory disorders following infection	Chronic fatigue syndrome	1	0
			Guillain-Barre syndrome	5	0
			Hepatitis chronic active	2	0
	Bacterial infectious disorders	Bacterial infections NEC	Bacterial infection	4	0
			Cellulitis	6	0
			Cellulitis orbital	3	0
			Folliculitis	1	0
		Clostridia infections	Botulism	10	0
		Escherichia infections	Escherichia infection	1	0
		Staphylococcal infections	Furuncle	1	0
	Fungal infectious disorders	Candida infections	Oral candidiasis	5	0
		Fungal infections NEC	Onychomycosis	1	0
	Infections - pathogen unspecified	Bone and joint infections	Intervertebral discitis	1	0
		Dental and oral	Oral infection	1	0

soft tissue infections	Sialoadenitis	1	0
	Tooth infection	1	0
Ear infections	Ear infection	3	0
	Labyrinthitis	1	0
	Mastoiditis	1	0
	Otitis media	1	0
Eye and eyelid infections	Conjunctivitis	1	0
	Hordeolum	1	0
Infections NEC	Abscess	2	0
	Abscess rupture	1	0
	Administration site infection	1	0
	Infection	10	0
	Injection site abscess	1	0
	Injection site infection	3	0
	Mediastinitis	1	0
	Post procedural infection	1	0
	Purulent discharge	1	0
	Respiratory tract infection	1	0
Lower respiratory tract and lung infections	Bronchitis	1	0
	Lower respiratory tract infection	9	0
	Pneumonia	10	5
	Pneumonia aspiration	5	2
Male reproductive tract infections	Orchitis	1	0
Muscle and soft tissue infections	Necrotising fasciitis	1	0
Sepsis, bacteraemia, viraemia and	Sepsis	6	1
	Septic shock	1	1
	Urosepsis	2	1
Skin structures and soft tissue infections	Injection site pustule	1	0
	Pustule	1	0
	Rash pustular	2	0
	Subcutaneous abscess	1	0
Upper respiratory tract infections	Nasopharyngitis	1	0
	Pharyngitis	2	0
	Rhinitis	1	0
	Sinusitis	7	0
	Tonsillitis	1	0
	Upper respiratory tract infection	2	0

		Urinary tract infections	Cystitis	2	0
			Kidney infection	1	0
			Urinary tract infection	18	0
	Mycobacterial infectious disorders	Atypical mycobacterial infections	Atypical mycobacterial infection	1	0
			Mycobacterial infection	1	0
			Mycobacterium abscessus infection	1	0
	Viral infectious disorders	Coronavirus infections	COVID-19	8	0
			COVID-19 pneumonia	1	0
			Suspected COVID-19	1	0
		Hepatitis virus infections	Acute hepatitis B	1	0
		Herpes viral infections	Oral herpes	1	0
		Influenza viral infections	Influenza	3	0
		Viral infections NEC	Gastroenteritis viral	1	0
			Viral infection	6	0
		Total		152	10
Injury, poisoning and procedural complications	Administration site reactions	Administration site reactions NEC	Administration site acne	1	0
			Administration site infection	1	0
			Administration site necrosis	1	0
			Administration site rash	1	0
			Administration site swelling	1	0
			Puncture site haemorrhage	1	0
		Application and instillation site reactions	Application site erythema	1	0
			Application site swelling	1	0
		Application site reactions	Application site erythema	1	0
			Application site swelling	1	0
		Implant and catheter site reactions	Catheter site haemorrhage	1	0
		Injection site reactions	Injection site abscess	1	0
			Injection site alopecia	1	0

Injection site bruising	21	0
Injection site discolouration	2	0
Injection site discomfort	5	0
Injection site dryness	1	0
Injection site erythema	16	0
Injection site fibrosis	1	0
Injection site granuloma	2	0
Injection site haematoma	1	0
Injection site haemorrhage	2	0
Injection site hypersensitivity	9	0
Injection site hypoaesthesia	4	0
Injection site indentation	5	0
Injection site induration	4	0
Injection site infection	3	0
Injection site injury	1	0
Injection site mass	40	0
Injection site movement impairment	1	0
Injection site muscle atrophy	1	0
Injection site muscle weakness	1	0
Injection site nerve damage	1	0
Injection site nodule	5	0
Injection site pain	79	0
Injection site pallor	1	0
Injection site papule	2	0
Injection site paraesthesia	3	0
Injection site pruritus	12	0

		Injection site pustule	1	0
		Injection site rash	8	0
		Injection site reaction	6	0
		Injection site scar	1	0
		Injection site swelling	40	0
		Injection site ulcer	1	0
		Injection site vesicles	1	0
Bone and joint injuries	Fractures and dislocations NEC	Joint dislocation	7	0
Exposures, chemical injuries and poisoning	Chemical injuries	Chemical peritonitis	1	0
	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	6	0
		Maternal exposure during pregnancy	4	0
	Occupational exposures	Occupational exposure to product	1	0
	Poisoning and toxicity	Dermatitis contact	1	0
		Hepatotoxicity	1	0
		Neuromuscular toxicity	13	0
		Poisoning	1	0
		Substance-induced psychotic disorder	2	0
		Systemic toxicity	1	0
		Toxicity to various agents	7	0
Injuries by physical agents	Heat injuries (excl thermal burns)	Heat stroke	1	0
	Radiation injuries	Sunburn	1	0
Injuries NEC	Cardiovascular injuries	Vascular injury	1	0
	Cerebral injuries NEC	Subarachnoid haemorrhage	2	0
	Cranial nerve injuries	Optic nerve injury	1	0

Ear injuries NEC	Tympanic membrane perforation	1	0
Eye injuries NEC	Corneal perforation	2	0
	Eye contusion	2	0
	Eye injury	2	0
	Open globe injury	1	0
	Vitreous detachment	1	0
Muscle, tendon and ligament injuries	Muscle injury	1	0
Nerve injuries NEC	Nerve injury	5	0
Non-site specific injuries NEC	Accident	1	0
	Arthropod bite	1	0
	Asphyxia	1	0
	Fall	4	0
Skin injuries NEC	Blister	8	0
	Contusion	23	0
	Scar	8	0
Spinal cord injuries NEC	Post-traumatic headache	1	0
Medication errors and other product use errors and issues	Accidental exposures to product	1	0
	Medication errors, product use errors and issues NEC	Circumstance or information capable of leading to medication error	0
		Drug effective for unapproved indication	0
		Drug ineffective for unapproved indication	0
		Medication error	0
		Prescription drug used without a prescription	0
		Product use in unapproved indication	0
		Treatment noncompliance	0
		Wrong technique in product usage process	0
	Product administration	Accidental overdose	0

	errors and issues	Counterfeit product administered	1	0	
		Inappropriate schedule of product administration	3	0	
		Incorrect dose administered	4	0	
		Incorrect drug administration rate	1	0	
		Incorrect route of product administration	14	0	
		Product administered at inappropriate site	3	0	
		Product administered by wrong person	1	0	
		Product administration error	6	0	
		Product dose omission issue	1	0	
		Wrong product administered	1	0	
	Product preparation errors and issues	Product preparation error	21	0	
		Product preparation issue	14	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	Intentional product misuses	Intentional product misuse	1	0
		Off label uses	Off label use	194	0
Overdoses and underdoses NEC	Overdoses NEC	Overdose	22	0	
		Prescribed overdose	9	0	
	Underdoses NEC	Underdose	1	0	
Procedural related injuries and complications NEC	Cardiac and vascular procedural complications	Phlebitis	1	1	
		Vascular pseudoaneurysm	1	0	

			Vascular pseudoaneurysm ruptured	1	1
			Vein collapse	1	0
		Gastrointestinal and hepatobiliary procedural complications	Procedural nausea	1	0
		Musculoskeletal procedural complications	Intervertebral discitis	1	0
		Neurological and psychiatric procedural complications	Mephisto sign	4	0
		Non-site specific procedural complications	Post procedural infection	1	0
		Skin procedural complications	Dermal filler reaction	1	0
			Skin procedural complication	1	0
		Transfusion related complications	Serum sickness	1	0
		Urinary tract procedural complications	Bladder perforation	1	0
		Total		509	2
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	1	0
		Heart rate and pulse investigations	Heart rate decreased	1	0
			Heart rate increased	4	0
			Heart rate irregular	3	0
			Pulse abnormal	2	0
		Vascular tests NEC (incl blood pressure)	Blood pressure abnormal	1	0
			Blood pressure decreased	2	0
			Blood pressure increased	4	0
	Endocrine investigations (incl sex hormones)	Reproductive hormone analyses	Blood oestrogen decreased	1	0
	Enzyme investigations NEC	Skeletal and cardiac muscle analyses	Blood creatine phosphokinase increased	2	0

Haematology investigations (incl blood groups)	Platelet analyses	Mean platelet volume increased	1	0
	Red blood cell analyses	Haematocrit increased	1	0
		Haemoglobin decreased	1	0
		Haemoglobin increased	1	0
		Red blood cell count increased	1	0
Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	1	0
		Blood bilirubin increased	2	0
		Liver function test abnormal	2	0
Immunology and allergy investigations	Immunoglobulin analyses	Blood immunoglobulin E increased	1	0
	Immunology analyses NEC	Neutralising antibodies	1	0
Lipid analyses	Cholesterol analyses	Blood cholesterol increased	1	0
	Triglyceride analyses	Blood triglycerides increased	1	0
Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Blood lactic acid increased	1	0
		Oxygen saturation decreased	5	0
	Vitamin analyses	Vitamin D decreased	1	0
Microbiology and serology investigations	Bacteria identification and serology (excl mycobacteria)	Citrobacter test positive	1	0
		Pseudomonas test positive	1	0
Neurological, special senses and psychiatric investigations	Neurologic diagnostic procedures	Neurotransmitter level altered	1	0
	Ophthalmic function diagnostic procedures	Intraocular pressure increased	1	0
Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature increased	3	0
		General physical condition abnormal	2	0
		Head lag	1	0

			Respiratory rate increased	1	0
			Weight decreased	15	0
	Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	1	0
		Protein analyses NEC	C-reactive protein abnormal	1	0
			C-reactive protein increased	1	0
	Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine increased	1	0
		Urinalysis NEC	Blood urine present	1	0
		Urinary tract function analyses NEC	Residual urine volume increased	1	0
			Urodynamics measurement abnormal	1	0
	Toxicology and therapeutic drug monitoring	Therapeutic drug monitoring analyses	Drug specific antibody present	3	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood iron decreased	2	0
			Blood sodium decreased	1	0
	Total			64	0
Metabolism and nutrition disorders	Acid-base disorders	Respiratory acidoses	Respiratory failure	5	1
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	11	0
			Eating disorder	1	0
		General nutritional disorders NEC	Abnormal loss of weight	5	0
			Feeding disorder	4	0
			Malnutrition	1	0
			Starvation	1	0
			Thirst	2	0
	Electrolyte and fluid balance conditions	Sodium imbalance	Hyponatraemia	1	0
		Total fluid volume decreased	Dehydration	3	0
		Total fluid volume increased	Fluid retention	2	0
			Oedema	11	0
			Oedema peripheral	3	0
	Food intolerance syndromes	Food malabsorption	Alcohol intolerance	1	0

		and intolerance syndromes (excl sugar intolerance)	Food intolerance	3	0
			Gluten sensitivity	1	0
			Histamine intolerance	4	0
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Type 1 diabetes mellitus	1	0
	Lipid metabolism disorders	Lipid metabolism and deposit	Facial wasting	2	0
			Lipoedema	1	0
			Xanthelasma	1	0
	Metabolism disorders NEC	Cell metabolism disorders NEC	Mitochondrial DNA mutation	1	0
	Total			59	1
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone and joint infections (excl arthritis)	Intervertebral discitis	1	0
		Bone disorders NEC	Bone loss	2	0
		Bone related signs and symptoms	Bone pain	1	0
			Pain in jaw	12	0
			Spinal pain	1	0
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Polymyalgia rheumatica	1	0
		Lupus erythematosus (incl subtypes)	Systemic lupus erythematosus	1	0
	Joint disorders	Arthropathies NEC	Arthritis	1	0
			Arthropathy	2	0
		Joint dislocations	Joint dislocation	7	0
		Joint related disorders NEC	Temporomandibular joint syndrome	2	0
			Temporomandibular pain and dysfunction syndrome	2	0
		Joint related signs and symptoms	Arthralgia	19	0
			Joint range of motion decreased	1	0
			Joint stiffness	2	0
			Joint swelling	2	0
		Rheumatoid arthropathies	Rheumatoid arthritis	1	0
	Muscle disorders	Muscle infections and inflammations	Myositis	1	0
		Muscle injuries	Muscle injury	1	0
		Muscle pains	Fibromyalgia	1	0

		Myalgia	18	0
Muscle related signs and symptoms NEC		Chills	6	0
		Injection site muscle atrophy	1	0
		Mephisto sign	4	0
		Muscle atrophy	8	0
		Muscle contractions involuntary	4	0
		Muscle discomfort	1	0
		Muscle disorder	4	0
		Muscle fatigue	6	0
		Muscle hypertrophy	1	0
		Muscle spasms	29	0
		Muscle swelling	2	0
		Muscle tightness	7	0
		Muscle twitching	15	0
		Myokymia	1	0
		Neuromyopathy	1	0
		Restless legs syndrome	1	0
	Muscle tone abnormalities	Hypotonia	3	0
		Muscle rigidity	1	0
		Muscle spasticity	6	0
		Stiff leg syndrome	1	0
		Torticollis	39	0
		Trismus	3	0
	Muscle weakness conditions	Injection site muscle weakness	1	0
		Motor dysfunction	1	0
		Muscular weakness	83	0
	Myasthenia gravis and related conditions	Myasthenia gravis	1	0
		Ocular myasthenia	1	0
Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)	Musculoskeletal and connective tissue	Facial asymmetry	11	0
		Nose deformity	1	0
		Spine and neck deformities	1	0
Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Back disorder	1	0
		Contusion	23	0
		Dysstasia	5	0
		Gait disturbance	7	0

			Mastication disorder	3	0
			Mobility decreased	5	0
			Muscle contracture	1	0
			Musculoskeletal disorder	2	0
			Musculoskeletal stiffness	13	0
			Posture abnormal	4	0
		Musculoskeletal and connective tissue infections and inflammations NEC	Necrotising fasciitis	1	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	12	0
			Flank pain	1	0
			Limb discomfort	4	0
			Musculoskeletal chest pain	1	0
			Musculoskeletal pain	1	0
			Neck pain	24	0
			Pain in extremity	18	0
	Tendon, ligament and cartilage disorders	Tendon disorders	Tendon discomfort	1	0
	Total			321	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasms malignant and unspecified (incl	Breast and nipple neoplasms	Breast cancer	7	0
			Breast cancer female	1	0
	Cutaneous neoplasms benign	Skin cysts and polyps	Dermal cyst	1	0
	Gastrointestinal neoplasms malignant and unspecified	Gastrointestinal neoplasms malignant NEC	Gastrointestinal carcinoma	1	0
		Pancreatic neoplasms malignant (excl islet cell and carcinoid)	Pancreatic carcinoma	1	0
	Haematopoietic neoplasms (excl leukaemias and lymphomas)	Myeloproliferative disorders (excl leukaemias)	Polycythaemia vera	1	0
	Miscellaneous and site unspecified neoplasms benign	Aural neoplasms benign	Cholesteatoma	1	0

		Cardiovascular neoplasms benign	Haemangioma	3	0
		Neoplasms benign site unspecified NEC	Cyst	1	0
	Neoplasm related morbidities	Oncologic complications and emergencies	Brain fog	14	0
		Paraneoplastic syndromes NEC	Acanthosis nigricans	1	0
	Renal and urinary tract neoplasms benign	Urinary tract neoplasms benign	Urinary bladder adenoma	2	0
	Renal and urinary tract neoplasms malignant and unspecified	Bladder neoplasms malignant	Bladder cancer	1	0
		Urinary tract neoplasms unspecified malignancy NEC	Bladder neoplasm	1	0
	Reproductive neoplasms female malignant and unspecified	Cervix neoplasms malignant	Cervix carcinoma	1	0
		Ovarian neoplasms malignant (excl germ cell)	Ovarian cancer	1	0
	Reproductive neoplasms male malignant and unspecified	Prostatic neoplasms malignant	Prostate cancer	1	0
	Respiratory and mediastinal neoplasms malignant and unspecified	Respiratory tract and pleural neoplasms malignant cell type unspecified NEC	Throat cancer	1	0
	Skin neoplasms malignant and unspecified	Skin neoplasms malignant and unspecified (excl melanoma)	Basal cell carcinoma	1	0
	Total			41	0
Nervous system disorders	Central nervous system infections and inflammations	Myelitis (incl infective)	Myelitis transverse	2	0

Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral haemorrhage	2	0
		Cerebral ischaemia	1	0
		Cerebrovascular accident	7	0
		Subarachnoid haemorrhage	2	0
		Thrombotic stroke	1	0
	Central nervous system vascular disorders NEC	Brain hypoxia	1	0
	Transient cerebrovascular events	Transient ischaemic attack	2	0
Cranial nerve disorders (excl neoplasms)	Auditory nerve disorders	Deafness neurosensory	1	0
		Tinnitus	17	0
	Eye movement disorders	VIth nerve paralysis	1	0
	Facial cranial nerve disorders	Bell's palsy	11	0
		Brow ptosis	25	0
		Facial paralysis	39	0
		Facial paresis	33	0
		Facial spasm	3	0
		Hyperacusis	3	0
	Hypoglossal nerve disorders	Tongue paralysis	2	0
	Mixed cranial nerve disorders	Bulbar palsy	3	0
	Olfactory nerve disorders	Anosmia	1	0
	Optic nerve disorders NEC	Optic nerve injury	1	0
		Optic neuritis	1	0
	Trigeminal disorders	Trigeminal neuralgia	1	0
	Vagus nerve disorders	Vocal cord paralysis	5	0
Demyelinating disorders	Multiple sclerosis acute and progressive	Multiple sclerosis relapse	1	0
Encephalopathies	Encephalopathies NEC	Encephalopathy	2	0
Headaches	Headaches NEC	Cluster headache	1	0
		Headache	148	0
		Post-traumatic headache	1	0
		Temporomandibular joint syndrome	2	0

		Temporomandibular pain and dysfunction syndrome	2	0
		Tension headache	8	0
	Migraine headaches	Hemiplegic migraine	1	0
		Migraine	35	0
		Vestibular migraine	2	0
Mental impairment disorders	Dementia (excl Alzheimer's type)	Progressive supranuclear palsy	1	0
		Memory loss (excl dementia)		
	Memory loss (excl dementia)	Amnesia	3	0
		Memory impairment	5	0
	Mental impairment (excl dementia and memory loss)	Cognitive disorder	3	0
		Disturbance in attention	6	0
		Mental impairment	1	0
Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	8	0
		Hypokinesia	1	0
		Motor dysfunction	1	0
		Movement disorder	3	0
		Psychomotor hyperactivity	1	0
	Dystonias	Dystonia	1	0
		Oculogyric crisis	1	0
		Opisthotonus	1	0
		Torticollis	39	0
		Trismus	3	0
	Paralysis and paresis (excl cranial nerve)	Hemiparesis	6	0
		Monoplegia	1	0
		Paralysis	10	0
		Paraplegia	1	0
		Quadriplegia	1	0
	Parkinson's disease and parkinsonism	Parkinsonism	1	0
		Reduced facial expression	1	0
	Tremor (excl congenital)	Head titubation	1	0
		Intention tremor	1	0
		Tremor	19	0
Neurological disorders NEC	Abnormal reflexes	Reflexes abnormal	1	0
	Coordination and balance disturbances	Balance disorder	9	0
		Coordination abnormal	3	0
		Dysstasia	5	0

Cortical dysfunction NEC	Aphasia	5	0
	Apraxia	1	0
	Autoscopy	1	0
	Confusional state	13	0
	Dyslexia	1	0
	Dyspraxia	1	0
Disturbances in consciousness NEC	Lethargy	8	0
	Loss of consciousness	9	0
	Near death experience	1	0
	Sedation	1	0
	Somnolence	11	0
	Syncope	19	0
Nervous system disorders NEC	Cerebral disorder	2	0
	Nerve injury	5	0
	Nervous system disorder	4	0
Neurological signs and symptoms NEC	Agitation	1	0
	Brain fog	14	0
	Clonus	1	0
	Disorientation	6	0
	Dizziness	92	0
	Dizziness exertional	1	0
	Dizziness postural	4	0
	Exaggerated startle response	2	0
	Eye movement disorder	1	0
	Gait disturbance	7	0
	Gait inability	1	0
	Head discomfort	17	0
	Heterophoria	1	0
	Mobility decreased	5	0
	Posture abnormal	4	0
	Presyncope	7	0
	Thinking abnormal	1	0
	Unresponsive to stimuli	1	0
Paraesthesias and dysaesthesias	Anaesthesia	1	0
	Burning sensation	23	0
	Formication	2	0
	Hypoaesthesia	49	0
	Hypoaesthesia oral	8	0

			Hypoaesthesia teeth	1	0
			Injection site hypoaesthesia	4	0
			Injection site paraesthesia	3	0
			Paraesthesia	49	0
			Paraesthesia oral	5	0
			Reversed hot-cold sensation	1	0
			Skin burning sensation	8	0
		Pupillary signs	Mydriasis	2	0
		Sensory abnormalities NEC	Ageusia	1	0
			Dysgeusia	7	0
			Electric shock sensation	7	0
			Keratoneuralgia	1	0
			Neuralgia	8	0
			Restless legs syndrome	1	0
			Sensory disturbance	7	0
			Sensory loss	3	0
			Taste disorder	3	0
		Speech and language abnormalities	Aphonia	5	0
			Dysarthria	16	0
			Dysphonia	20	0
			Incoherent	1	0
			Slow speech	1	0
			Speech disorder	14	0
		Vertigos NEC	Meniere's disease	1	0
			Motion sickness	1	0
			Vertigo	19	0
	Neurological disorders of the eye	Neurologic visual problems NEC	Blindness	3	0
			Blindness transient	2	0
			Diplopia	37	0
			Photopsia	2	0
			Strabismus	12	0
			Vision blurred	67	0
			Visual field defect	1	0
			Visual snow syndrome	1	0
		Ocular signs and symptoms NEC	Blepharospasm	10	0
			Eyelid ptosis	84	0
			Eyelid sensory disorder	2	0
			Ophthalmoplegia	2	0

		Photophobia	9	0
Neuromuscular disorders	Autonomic nervous system disorders	Anal incontinence	5	0
		Atonic urinary bladder	2	0
		Autonomic nervous system imbalance	1	0
		Incontinence	2	0
		Orthostatic hypotension	1	0
		Postural orthostatic tachycardia syndrome	3	0
		Urinary incontinence	9	0
	Motor neurone diseases	Motor neurone disease	1	1
	Muscle tone abnormal	Hypotonia	3	0
		Muscle rigidity	1	0
		Stiff leg syndrome	1	0
	Neuromuscular disorders NEC	Injection site muscle weakness	1	0
		Mastication disorder	3	0
		Muscle atrophy	8	0
		Muscle contractions involuntary	4	0
		Muscle spasticity	6	0
		Muscular weakness	83	0
		Neuromuscular toxicity	13	0
		Neuromyopathy	1	0
	Neuromuscular junction dysfunction	Myasthenia gravis	1	0
		Neuromuscular blockade	1	0
		Ocular myasthenia	1	0
Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	5	0
	Mononeuropathies	Carpal tunnel syndrome	1	0
Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	2	0
	Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	7	0

		Partial simple seizures NEC	Simple partial seizures	3	0
		Seizures and seizure disorders NEC	Epilepsy	9	0
			Partial seizures	3	0
			Seizure	20	0
	Sleep disturbances (incl subtypes)	Abnormal sleep-related events	Sleep paralysis	1	0
		Disturbances in initiating and maintaining sleep	Insomnia	25	0
		Narcolepsy and hypersomnia	Hypersomnia	1	0
	Spinal cord and nerve root disorders	Cervical spinal cord and nerve root disorders	Cervical spinal stenosis	1	0
		Spinal cord and nerve root disorders NEC	Hypertonic bladder	2	0
			Neurogenic bladder	2	0
			Radiculitis brachial	1	0
			Spinal pain	1	0
	Structural brain disorders	Structural brain disorders NEC	Brain injury	5	1
	Total			745	2
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions spontaneous	Abortion spontaneous	23	0
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature delivery	1	0
			Premature labour	2	0
	Maternal complications of pregnancy	Maternal complications of pregnancy NEC	Somatic symptom disorder of pregnancy	1	0
	Neonatal and perinatal conditions	Gestational age and weight conditions	Premature baby	1	0
	Pregnancy, labour, delivery and postpartum conditions	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	6	0
			Maternal exposure during pregnancy	4	0
		Normal pregnancy,	Live birth	1	0
			Pregnancy	10	0
	Total			31	0
Product issues	Device issues	Device issues NEC	Device dislocation	1	0
	Product quality, supply, distribution, manufacturing and	Counterfeit, falsified and substandard	Counterfeit product administered	1	0

	quality system issues	products	Suspected counterfeit product	2	0
		Product contamination and sterility issues	Product contamination	1	0
		Product packaging issues	Product container issue	1	0
			Product outer packaging issue	3	0
			Product packaging issue	1	0
			Product packaging quantity issue	1	0
		Product physical issues	Product reconstitution quality issue	1	0
		Product quality issues NEC	Product quality issue	4	0
			Product substitution issue	2	0
			Suspected product quality issue	1	0
		Total		18	0
	Psychiatric disorders	Adjustment disorders (incl subtypes)	Adjustment disorder with depressed mood	1	0
		Anxiety disorders and symptoms	Agitation	1	0
			Anxiety	60	0
			Nervousness	5	0
			Stress	3	0
			Fear symptoms	1	0
			Fear of injection	2	0
			Social fear	1	0
			Obsessive-compulsive disorders and symptoms	1	0
			Panic attacks and disorders	29	0
			Panic reaction	4	0
		Stress disorders	Post-traumatic stress disorder	1	0
		Changes in physical activity	Decreased physical activity levels	1	0
			Increased physical activity levels	1	0

	Stereotypies and automatisms	Bruxism	1	0
Cognitive and attention disorders and disturbances	Cognitive and attention disorders and disturbances NEC	Brain fog	14	0
		Cognitive disorder	3	0
		Disturbance in attention	6	0
		Mental impairment	1	0
	Specific cognitive ability disturbances	Aphasia	5	0
		Apraxia	1	0
		Dyslexia	1	0
Communication disorders and disturbances	Communications disorders	Aphonia	5	0
		Communication disorder	1	0
	Speech and language usage disturbances	Slow speech	1	0
		Speech disorder	14	0
	Speech articulation and	Dysarthria	16	0
		Dysphonia	20	0
Deliria (incl confusion)	Confusion and disorientation	Confusional state	13	0
		Disorientation	6	0
Dementia and amnesic conditions	Amnesic symptoms	Amnesia	3	0
		Memory impairment	5	0
Depressed mood disorders and disturbances	Depressive disorders	Depression	14	0
		Major depression	1	0
	Mood alterations with depressive symptoms	Depressed mood	9	0
		Feeling of despair	1	0
Dissociative disorders	Dissociative states	Dissociation	2	0
Disturbances in thinking and perception	Hallucinations (excl sleep-	Formication	2	0
		Hallucination	2	0
	Perception disturbances NEC	Autoscopy	1	0
		Derealisation	1	0
		Near death experience	1	0
	Thinking disturbances	Incoherent	1	0
		Thinking abnormal	1	0
Eating disorders and disturbances	Eating disorders NEC	Eating disorder	1	0
		Feeding disorder	4	0
Mood disorders and disturbances NEC	Affect alterations NEC	Inappropriate affect	1	0
	Emotional and mood disturbances NEC	Anger	3	0
		Emotional disorder	2	0
		Emotional distress	5	0

		Irritability	2	0
	Fluctuating mood symptoms	Mood swings	2	0
	Mood disorders NEC	Asthenia	63	0
		Lethargy	8	0
Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	1	0
		Social avoidant behaviour	2	0
	Personality disorders NEC	Self esteem decreased	1	0
Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	1	0
		Behaviour disorder	1	0
		Breath holding	1	0
	Psychiatric symptoms NEC	Exaggerated startle response	2	0
		Helplessness	1	0
		Hyperventilation	3	0
		Psychiatric symptom	5	0
		Reduced facial expression	1	0
		Throat tightness	5	0
Psychiatric disorders NEC	Mental disorders due to a general medical condition NEC	Brain injury	5	1
	Mental disorders NEC	Mental disorder	1	0
Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Substance-induced psychotic disorder	2	0
Sexual dysfunctions, disturbances and gender identity	Sexual arousal disorders	Erectile dysfunction	1	0
	Sexual desire disorders	Loss of libido	1	0
Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	25	0
	Dyssomnias	Hypersomnia	1	0
		Somnolence	11	0
	Narcolepsy and associated conditions	Sleep paralysis	1	0
	Parasomnias	Nightmare	1	0
	Sleep disorders NEC	Sleep disorder	2	0

	Somatic symptom and related disorders	Somatic symptom disorders	Somatic symptom disorder of pregnancy	1	0
			Tension headache	8	0
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour	Suicidal ideation	9	0
			Total	252	1
Renal and urinary disorders	Bladder and bladder neck disorders (excl calculi)	Bladder disorders NEC	Bladder disorder	2	0
			Bladder necrosis	1	0
			Bladder perforation	1	0
		Bladder infections and inflammations	Cystitis	2	0
			Cystitis interstitial	1	0
		Bladder neoplasms	Bladder cancer	1	0
			Bladder neoplasm	1	0
			Urinary bladder adenoma	2	0
		Myoneurogenic bladder disorders	Atonic urinary bladder	2	0
			Hypertonic bladder	2	0
			Neurogenic bladder	2	0
	Genitourinary tract disorders NEC	Genital and urinary tract disorders NEC	Urinary tract disorder	1	0
			Urinary tract infection	18	0
		Genitourinary tract infections and	Urosepsis	2	1
	Nephropathies	Glomerulonephritis and nephrotic syndrome	Granulomatosis with polyangiitis	1	0
		Nephritis NEC	Tubulointerstitial nephritis	1	0
	Renal disorders (excl nephropathies)	Renal disorders NEC	Fluid retention	2	0
			Acute kidney injury	2	0
		Renal failure and impairment	Anuria	1	0
			Renal failure	2	1
			Azotaemia	1	0
		Renal failure complications	Kidney infection	1	0
		Renal infections and inflammations (excl nephritis)			

		Renal structural abnormalities and trauma	Kidney enlargement	1	0
		Renal vascular and ischaemic conditions	Renal tubular necrosis	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Bladder discomfort	1	0
			Bladder pain	1	0
			Dysuria	3	0
			Incontinence	2	0
			Micturition urgency	2	0
			Pollakiuria	2	0
			Urinary incontinence	9	0
			Urinary retention	11	0
		Urinary abnormalities	Chromaturia	2	0
			Haematuria	4	0
			Urine abnormality	1	0
		Urinary tract signs and symptoms NEC	Flank pain	1	0
			Pelvic pain	1	0
			Renal pain	3	0
	Total			71	2
Reproductive system and breast disorders	Breast disorders	Benign and malignant breast neoplasms	Breast cancer	7	0
			Breast cancer female	1	0
		Breast disorders NEC	Breast mass	1	0
	Cervix disorders (excl infections and inflammations)	Cervix neoplasms	Cervix carcinoma	1	0
	Female reproductive tract infections and inflammations	Vaginal and vulval infections and inflammations	Noninfective bartholinitis	1	0
	Male reproductive tract infections and inflammations	Testicular and epididymal infections and inflammations	Orchitis	1	0
	Menopause related conditions	Menopausal effects NEC	Hot flush	2	0
	Menstrual cycle and uterine bleeding disorders	Menstruation with decreased bleeding	Amenorrhoea	1	0
	Ovarian and fallopian tube disorders	Ovarian and fallopian tube cysts and neoplasms	Ovarian cancer	1	0

	Prostatic disorders (excl infections and inflammations)	Prostatic neoplasms and hypertrophy	Prostate cancer	1	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Haematuria	4	0
			Oedema genital	1	0
			Pelvic pain	1	0
	Sexual function and fertility disorders	Erection and ejaculation conditions and disorders	Erectile dysfunction	1	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal signs and symptoms	Vulvovaginal pain	2	0
	Total			24	0
	Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchiectasis	1	0
			Asthma	3	0
		Bronchospasm and obstruction	Chronic obstructive pulmonary disease	1	0
			Wheezing	5	0
		Lower respiratory tract disorders (excl obstruction and infection)	Granulomatosis with polyangiitis	1	0
			Acute respiratory distress syndrome	1	0
			Pulmonary oedema	1	0
		Pleural disorders	Pneumothorax and pleural effusions NEC	1	0
		Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	3	0
		Respiratory disorders NEC	Breath holding	1	0
			Dyspnoea	73	0
			Dyspnoea exertional	2	0
			Hyperventilation	3	0
			Respiration abnormal	2	0
			Respiratory arrest	1	0
			Conditions associated with abnormal gas		
			Asphyxia	1	0
			Brain hypoxia	1	0
			Cyanosis	3	0

	Coughing and associated symptoms	Cough	7	0	
		Productive cough	3	0	
	Respiratory failures (excl neonatal)	Cardio-respiratory arrest	1	0	
		Cardiopulmonary failure	1	0	
		Respiratory failure	5	1	
	Respiratory tract disorders NEC	Aspiration	3	0	
		Pulmonary mass	1	0	
		Respiratory disorder	2	0	
		Respiratory tract oedema	1	0	
	Respiratory tract infections	Lower respiratory tract infections NEC	Bronchitis	1	0
Lower respiratory tract infection			9	0	
Pneumonia			10	5	
Pneumonia aspiration			5	2	
Respiratory tract infections NEC		Respiratory tract infection	1	0	
Upper respiratory tract infections NEC		Nasopharyngitis	1	0	
		Pharyngitis	2	0	
		Rhinitis	1	0	
		Sinusitis	7	0	
		Tonsillitis	1	0	
		Upper respiratory tract infection	2	0	
Viral lower respiratory tract infections		COVID-19	8	0	
		COVID-19 pneumonia	1	0	
		Suspected COVID-19	1	0	
Viral upper respiratory tract infections		Influenza	3	0	
Respiratory tract neoplasms		Upper respiratory tract neoplasms	Throat cancer	1	0
Respiratory tract signs and symptoms		Respiratory signs and symptoms NEC	Chest discomfort	9	0
	Chest pain		14	0	
	Respiratory symptom		1	0	
	Suffocation feeling		1	0	
	Upper respiratory tract	Aphonia	5	0	
		Choking	7	0	

	signs and symptoms	Dry throat	5	0
		Dysphonia	20	0
		Increased upper airway secretion	1	0
		Increased viscosity of upper respiratory secretion	1	0
		Oropharyngeal pain	12	0
		Paranasal sinus discomfort	3	0
		Rhinorrhoea	2	0
		Sinus pain	1	0
		Sneezing	1	0
		Speech disorder	14	0
		Throat tightness	5	0
		Upper-airway cough syndrome	1	0
		Yawning	1	0
Thoracic disorders (excl lung and pleura)	Diaphragmatic disorders	Diaphragmatic disorder	1	0
	Mediastinal disorders	Mediastinitis	1	0
	Thoracic musculoskeletal disorders	Musculoskeletal chest pain	1	0
Upper respiratory tract disorders (excl infections)	Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	Vocal cord paralysis	5	0
	Laryngeal spasm, oedema and obstruction	Angioedema	6	0
		Laryngomalacia	1	0
		Laryngospasm	1	0
		Stridor	2	0
	Nasal congestion and inflammations	Nasal congestion	2	0
		Seasonal allergy	1	0
	Nasal disorders NEC	Anosmia	1	0
		Epistaxis	1	0
		Nasal oedema	1	0
	Paranasal sinus disorders (excl infections and neoplasms)	Sinus disorder	2	0
	Pharyngeal disorders (excl	Pharyngeal disorder	1	0

		infections and neoplasms)	Pharyngeal swelling	7	0
	Total			224	8
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	6	0
			Circumoral swelling	1	0
			Eyelid oedema	2	0
			Face oedema	10	0
			Lip swelling	9	0
			Mouth swelling	1	0
			Orbital swelling	1	0
			Periorbital oedema	3	0
			Periorbital swelling	35	0
			Swelling face	51	0
			Swelling of eyelid	12	0
			Swollen tongue	11	0
		Urticarias	Urticaria	20	0
			Urticaria cholinergic	1	0
	Cornification and dystrophic skin disorders	Skin dystrophies	Skin wrinkling	9	0
		Skin hyperplasias and hypertrophies	Acanthosis nigricans	1	0
		Skin hypoplasias and atrophies	Skin atrophy	1	0
	Cutaneous neoplasms benign	Skin cysts and polyps	Dermal cyst	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	8	0
			Dermatitis bullous	3	0
			Injection site vesicles	1	0
			Pemphigoid	1	0
		Connective tissue disorders	Brow ptosis	25	0
			Systemic lupus erythematosus	1	0
		Dermal and epidermal conditions NEC	Cheilitis	1	0
			Cutaneous contour deformity	1	0
			Dry skin	4	0
			Eyelid disorder	9	0
			Eyelid pain	1	0
			Eyelid skin dryness	1	0
			Hypoaesthesia	49	0
			Injection site discolouration	2	0

	Injection site dryness	1	0
	Injection site indentation	5	0
	Injection site pallor	1	0
	Injection site papule	2	0
	Jaundice	1	0
	Pain of skin	1	0
	Pallor	6	0
	Papule	5	0
	Paraesthesia	49	0
	Skin burning sensation	8	0
	Skin discolouration	11	0
	Skin disorder	5	0
	Skin indentation	2	0
	Skin induration	1	0
	Skin laxity	2	0
	Skin lesion	5	0
	Skin necrosis	2	0
	Skin odour abnormal	1	0
	Skin reaction	1	0
	Skin swelling	6	0
	Skin tightness	7	0
	Skin warm	1	0
	Xanthelasma	1	0
Dermatitis and eczema	Blepharitis	3	0
	Dermatitis allergic	1	0
	Dermatitis contact	1	0
	Eczema	2	0
	Eczema eyelids	1	0
	Eyelid irritation	2	0
	Skin irritation	4	0
Dermatitis ascribed to specific agent	Dermal filler reaction	1	0
	Drug eruption	2	0
Erythemas	Application site erythema	1	0
	Erythema	39	0
	Erythema of eyelid	3	0
	Injection site erythema	16	0
Exfoliative conditions	Skin exfoliation	3	0
Granulomatous and deep cutaneous	Granuloma	1	0
	Granuloma annulare	1	0

	inflammatory conditions	Injection site granuloma	2	0
	Photosensitivity and photodermatosis conditions	Photodermatosis	1	0
		Photosensitivity reaction	5	0
		Sunburn	1	0
	Pruritus NEC	Eyelids pruritus	4	0
		Injection site pruritus	12	0
		Pruritus	27	0
	Psoriatic conditions	Psoriasis	1	0
	Pustular conditions	Injection site pustule	1	0
		Pustule	1	0
		Rash pustular	2	0
	Rashes, eruptions and exanthems NEC	Administration site rash	1	0
		Injection site rash	8	0
		Rash	43	0
		Rash erythematous	6	0
		Rash macular	10	0
		Rash maculo-papular	1	0
		Rash papular	3	0
		Rash pruritic	2	0
		Rash vesicular	3	0
	Scaly conditions	Dandruff	1	0
	Skin injuries and mechanical dermatoses	Contusion	23	0
		Injection site bruising	21	0
		Injection site scar	1	0
		Scar	8	0
		Skin procedural complication	1	0
Pigmentation disorders	Hyperpigmentation disorders	Melanosis	1	0
		Skin hyperpigmentation	1	0
	Pigmentation changes NEC	Pigmentation disorder	2	0
		Post inflammatory pigmentation change	1	0
Skin and subcutaneous tissue disorders NEC	Lipodystrophies	Facial wasting	2	0
	Panniculitides	Panniculitis	1	0
	Skin and subcutaneous	Adiposis dolorosa	1	0

	conditions NEC	Injection site nodule	5	0
		Skin mass	6	0
	Skin and subcutaneous malformations and anomalies NEC	Eyelid thickening	2	0
	Skin and subcutaneous tissue ulcerations	Injection site ulcer	1	0
Skin and subcutaneous tissue infections and infestations NEC	Skin and subcutaneous	Cellulitis	6	0
		Furuncle	1	0
	Skin and subcutaneous tissue fungal infections	Onychomycosis	1	0
	Skin and subcutaneous tissue infections	Folliculitis	1	0
		Subcutaneous abscess	1	0
Skin appendage conditions	Acnes	Acne	5	0
		Administration site acne	1	0
		Dermatitis acneiform	1	0
	Alopecias	Alopecia	15	0
		Androgenetic alopecia	1	0
		Injection site alopecia	1	0
		Madarosis	2	0
	Apocrine and eccrine gland disorders	Cold sweat	1	0
		Hyperhidrosis	14	0
		Night sweats	4	0
	Nail and nail bed conditions (excl infections and infestations)	Onychomadesis	1	0
	Pilar disorders NEC	Hair texture abnormal	2	0
		Trichotillomania	1	0
	Rosaceas	Rosacea	1	0
Skin neoplasms malignant and unspecified	Skin neoplasms malignant and unspecified (excl melanoma)	Basal cell carcinoma	1	0
Skin vascular abnormalities	Purpura and related conditions	Petechiae	1	0
	Skin haemorrhages	Skin haemorrhage	1	0

Social circumstances	Lifestyle issues	Skin vascular conditions NEC	Capillary fragility	1	0
			Cyanosis	3	0
			Peripheral coldness	2	0
		Skin vasomotor conditions	Flushing	6	0
			Livedo reticularis	2	0
			Vasodilatation	2	0
		Total		475	0
	Disability issues	Bedridden	Bedridden	1	0
			Impaired driving ability	3	0
			Impaired work ability	5	0
			Loss of personal independence in daily activities	2	0
			Walking disability	1	0
			Wheelchair user	1	0
		Social issues NEC	Impaired quality of life	2	0
			Patient dissatisfaction with treatment	1	0
	Total			13	0
Surgical and medical procedures	Eye therapeutic procedures	Corneal and scleral therapeutic procedures	Corneal transplant	1	0
		Eye therapeutic procedures NEC	Eye operation	1	0
	Gastrointestinal therapeutic procedures	Gastric therapeutic procedures	Gastric banding	1	0
	Head and neck therapeutic procedures	Dental and gingival therapeutic procedures	Endodontic procedure	1	0
		Tonsillar therapeutic procedures	Tonsillectomy	1	0
	Nervous system, skull and spine therapeutic procedures	Nervous system therapeutic procedures NEC	Central nervous system stimulation	1	0
	Renal and urinary tract therapeutic procedures	Therapeutic bladder catheterisation	Bladder catheterisation	1	0

	Skin and subcutaneous tissue therapeutic procedures	Skin and subcutaneous tissue therapeutic procedures NEC	Skin cosmetic procedure	1	0
		Skin grafts	Skin graft	1	0
	Therapeutic procedures and supportive care NEC	Anaesthesia and allied procedures	Nerve block	1	0
		Therapeutic procedures NEC	Cyst drainage	1	0
			Hospitalisation	1	0
			Mass excision	1	0
	Total			13	0
Vascular disorders	Aneurysms and artery dissections	Aortic aneurysms and dissections	Aortic aneurysm rupture	1	0
	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Cerebrovascular and spinal necrosis and vascular insufficiency	Brain hypoxia	1	0
			Cerebral ischaemia	1	0
			Transient ischaemic attack	2	0
		Coronary necrosis and vascular insufficiency	Acute myocardial infarction	1	1
			Angina pectoris	1	0
			Myocardial infarction	3	0
		Gastrointestinal necrosis and vascular insufficiency	Intestinal ischaemia	1	0
		Peripheral vasoconstriction, necrosis and vascular	Peripheral coldness	2	0
			Raynaud's phenomenon	1	0
		Site specific necrosis and vascular insufficiency NEC	Bladder necrosis	1	0
	Decreased and nonspecific blood pressure disorders and shock	Blood pressure disorders NEC	Autonomic nervous system imbalance	1	0
		Circulatory collapse and shock	Anaphylactic shock	1	0
			Circulatory collapse	1	0
			Dizziness	92	0
			Dizziness exertional	1	0
			Dizziness postural	4	0
			Heat stroke	1	0

		Presyncope	7	0
		Septic shock	1	1
		Shock	1	0
		Syncope	19	0
	Vascular hypotensive disorders	Anaphylactic reaction	9	0
		Hypotension	5	0
		Orthostatic hypotension	1	0
Embolism and thrombosis	Cerebrovascular embolism and thrombosis	Thrombotic stroke	1	0
	Non-site specific embolism and thrombosis	Thrombosis	2	0
	Peripheral embolism and thrombosis	Deep vein thrombosis	3	0
	Pulmonary embolism and thrombosis	Pulmonary embolism	3	0
	Retinal embolism and thrombosis	Retinal vein occlusion	2	0
Lymphatic vessel disorders	Lymphoedemas	Lymphoedema	1	0
Vascular disorders NEC	Cerebrovascular and spinal vascular disorders NEC	Cerebrovascular accident	7	0
		Hemiplegic migraine	1	0
		Migraine	35	0
	Non-site specific vascular disorders NEC	Acute respiratory distress syndrome	1	0
		Angiopathy	1	0
		Capillary fragility	1	0
		Superficial vein prominence	1	0
		Vascular pseudoaneurysm	1	0
		Vascular pseudoaneurysm ruptured	1	1
		Vasodilatation	2	0
		Vein collapse	1	0
		Vein discolouration	1	0
		Vein disorder	2	0
	Peripheral vascular disorders NEC	Cyanosis	3	0
		Flushing	6	0
		Hot flush	2	0

		Site specific vascular disorders NEC	Livedo reticularis	2	0
			Pallor	6	0
		Vascular neoplasms	Haemangioma	3	0
	Vascular haemorrhagic disorders	Bruising, ecchymosis and purpura	Contusion	23	0
			Eye contusion	2	0
			Injection site bruising	21	0
			Petechiae	1	0
		Gastrointestinal haemorrhages	Gastrointestinal haemorrhage	1	0
			Haematochezia	1	0
			Oesophageal intramural haematoma	1	0
		Haemorrhages NEC	Catheter site haemorrhage	1	0
			Epistaxis	1	0
			Haematoma	4	0
			Haematuria	4	0
			Haemorrhage	1	0
			Injection site haematoma	1	0
			Injection site haemorrhage	2	0
			Puncture site haemorrhage	1	0
			Skin haemorrhage	1	0
		Nervous system haemorrhagic disorders	Cerebral haemorrhage	2	0
			Subarachnoid haemorrhage	2	0
		Ocular haemorrhagic disorders	Conjunctival haemorrhage	2	0
			Vitreous haemorrhage	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	5	0
	Vascular infections and inflammations	Phlebitis NEC	Phlebitis	1	1
		Vasculitides NEC	Granulomatosis with polyangiitis	1	0
	Vascular injuries	Vascular injuries NEC	Vascular injury	1	0
	Total			267	4
Total reactions for drug					
Total reports for drug				1,535	
Total fatal outcome					23