

COVID-19 Moderna Vaccine Analysis Print

All UK spontaneous reports received up to 11/08/21 for COVID-19
Moderna vaccine analysis print

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Case Series Drug Analysis Print

Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 12-Aug-2021

Data Lock Date: 11-Aug-2021 18:30:09

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	108	0
Lymphadenitis	9	0
Lymphadenopathy	635	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	16	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	785	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	6	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	280	0
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiac failure congestive	1	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	13	0
Myocardial infarction	9	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	33	0
<i>Noninfectious pericarditis</i>		
Pericarditis	28	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	7	0
Bradycardia	7	0
Cardiac flutter	25	0
Extrasystoles	12	0
Tachycardia	26	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Atrial tachycardia	1	0
Sinus tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	3	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	463	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Male reproductive tract disorders congenital</i>		
Micropenis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	4	0
Ear discomfort	2	0
Ear disorder	1	0
Ear pain	92	0
Ear swelling	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
<i>Hearing losses</i>		
Deafness	13	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	13	0
Sudden hearing loss	5	0
<i>Hyperacusia</i>		
Hyperacusis	5	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	9	0
Tinnitus	143	0
Vertigo	105	0
Vertigo positional	2	0
Ear disorders SOC TOTAL	405	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
Ovulation delayed	8	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	2	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	1	0
Vitreous floaters	4	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	12	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	2	0
<i>Lacrimation disorders</i>		
Dry eye	9	0
Lacrimation increased	5	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
Swelling of eyelid	7	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye pain	98	0
Eye swelling	31	0
Ocular discomfort	2	0
Periorbital oedema	2	0
Periorbital swelling	6	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye inflammation	1	0
Eye irritation	7	0
Eye pruritus	14	0
Ocular hyperaemia	15	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	4	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	3	0
Foreign body sensation in eyes	1	0
Hypoaesthesia eye	1	0
Photophobia	27	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
Papilloedema	1	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic ischaemic neuropathy	1	0
<i>Orbital infections, inflammations and irritations</i>		
Orbital myositis	1	0
<i>Pupil disorders</i>		
Mydriasis	2	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0

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Eye disorders Eye disorders cont'd		
Astigmatism	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal haemorrhage	1	0
Retinal vein occlusion	1	0
Retinopathies NEC		
Acute zonal occult outer retinopathy	1	0
Serous retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	4	0
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	1	0
Visual colour distortions		
Cyanopsia	1	0
Visual disorders NEC		
Diplopia	12	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	124	0
Visual field disorders		
Visual field defect	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness	11	0
Blindness transient	1	0
Blindness unilateral	1	0
Visual acuity reduced	1	0
Visual impairment	18	0
Eye disorders SOC TOTAL	453	0

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Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal pains</i>		
Proctalgia	2	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	2	0
Crohn's disease	4	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	1	0
Hyperaesthesia teeth	4	0
Toothache	11	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	369	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	39	0
Epigastric discomfort	1	0
Eructation	4	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	4	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	25	0
Flatulence	12	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	111	0
Abdominal pain lower	8	0
Abdominal pain upper	243	0
Abdominal rigidity	1	0
Abdominal tenderness	2	0
Gastrointestinal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	16	0
Gastrooesophageal reflux disease	8	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Stomach mass	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	1	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Fistula of small intestine	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	47	0
Anal incontinence	3	0
Breath odour	3	0
Dysphagia	15	0
Odynophagia	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	3	0
Irritable bowel syndrome	5	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	6	0
Gingival swelling	4	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	4	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	6	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	1419	0
Retching	9	0
Vomiting	446	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
Haematochezia	4	0
Melaena	1	0
Upper gastrointestinal haemorrhage	2	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	41	0
Lip dry	4	0
Saliva altered	1	0
Salivary hypersecretion	5	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
Enlarged uvula	1	0
Lip blister	2	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip disorder	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral blood blister	2	0
Oral soft tissue signs and symptoms		
Coating in mouth	2	0
Hypoaesthesia oral	35	0
Lip discolouration	1	0
Lip pain	2	0
Lip pruritus	1	0
Oral discomfort	2	0
Oral mucosal roughening	1	0
Oral pain	8	0
Oral pruritus	1	0
Paraesthesia oral	60	0
Oral soft tissue swelling and oedema		
Lip swelling	58	0
Mouth swelling	9	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	2	0
Salivary gland enlargements		
Submaxillary gland enlargement	1	0
Stomatitis and ulceration		
Aphthous ulcer	3	0
Lip ulceration	2	0
Mouth ulceration	35	0
Stomatitis	2	0
Tongue disorders		
Glossitis	2	0
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	3	0
Tongue signs and symptoms		
Glossodynia	13	0
Swollen tongue	32	0
Tongue blistering	1	0
Tongue coated	2	0
Tongue discolouration	2	0
Tongue discomfort	2	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	1	0
Tooth missing		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	3235	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Puncture site bruise	5	0
Puncture site pain	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	5	0
Application site joint erythema	1	0
Application site pain	1	0
Application site pruritus	9	0
Application site rash	1	0
Application site swelling	2	0
Application site vesicles	4	0
Application site warmth	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	153	0
Chronic fatigue syndrome	1	0
Fatigue	1980	0
Malaise	320	0
<i>Death and sudden death</i>		
Death	7	7
<i>Febrile disorders</i>		
Pyrexia	1963	1
<i>Feelings and sensations NEC</i>		
Chills	1057	0
Feeling abnormal	169	0
Feeling cold	74	0
Feeling drunk	8	0
Feeling hot	140	0
Feeling jittery	7	0
Feeling of body temperature change	32	0
Hangover	8	0
Hunger	10	0
Sensation of blood flow	1	0
Sensation of foreign body	3	0
Temperature intolerance	13	0
Thirst	40	0
<i>Gait disturbances</i>		
Gait disturbance	14	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	6	0
Crying	18	0
Discharge	3	0
Energy increased	1	0
Exercise tolerance decreased	4	0
Foaming at mouth	2	0
Illness	148	0
Induration	5	0
Influenza like illness	206	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Irritability postvaccinal	1	0
Local reaction	11	0
Perforation	1	0
Peripheral swelling	995	0
Screaming	2	0
Secretion discharge	1	0
Swelling	512	0
Swelling face	60	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Inflammation	62	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site mass	1	0
Infusion site pain	4	0
Infusion site pruritus	1	0
Infusion site urticaria	2	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	4	0
Injection site bruising	9	0
Injection site discolouration	1	0
Injection site erythema	97	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	5	0
Injection site hypoaesthesia	4	0
Injection site indentation	1	0
Injection site inflammation	6	0
Injection site irritation	1	0
Injection site joint erythema	3	0
Injection site mass	98	0
Injection site oedema	2	0
Injection site pain	303	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	77	0
Injection site rash	140	0
Injection site reaction	11	0
Injection site swelling	46	0
Injection site urticaria	43	0
Injection site vesicles	1	0
Injection site warmth	48	0
Interactions		
Alcohol interaction	1	0
Drug interaction	1	0
Mass conditions NEC		
Cyst	4	0
Mass	16	0
Nodule	2	0
Mucosal findings abnormal		
Enanthema	1	0

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General disorders General disorders cont'd		
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema NEC		
Face oedema	1	0
Localised oedema	1	0
Oedema	3	0
Oedema peripheral	2	0
Pain and discomfort NEC		
Axillary pain	322	0
Chest discomfort	121	0
Chest pain	289	0
Discomfort	54	0
Facial pain	10	0
Inflammatory pain	1	0
Non-cardiac chest pain	1	0
Pain	970	0
Tenderness	87	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	5	0
Drug ineffective	8	0
Drug intolerance	1	0
Inadequate analgesia	2	0
No reaction on previous exposure to drug	1	0
Therapeutic response unexpected	2	0
Vaccination failure	1	0
Ulcers NEC		
Ulcer	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	11	0
Vaccination site discolouration	1	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	195	0
Vaccination site haemorrhage	2	0
Vaccination site hypoaesthesia	3	0
Vaccination site induration	14	0
Vaccination site inflammation	6	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	2	0
Vaccination site mass	46	0
Vaccination site movement impairment	6	0
Vaccination site oedema	1	0
Vaccination site pain	176	0
Vaccination site papule	2	0
Vaccination site pruritus	51	0
Vaccination site rash	96	0
Vaccination site reaction	2	0
Vaccination site swelling	118	0
Vaccination site urticaria	7	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site vesicles	1	0
Vaccination site warmth	87	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	2	0
General disorders SOC TOTAL	11751	8

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Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	3	0
<i>Cholestasis and jaundice</i>		
Jaundice cholestatic	2	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatic steatosis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	10	0

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	3	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	155	0
Infusion related hypersensitivity reaction	7	0
Multiple allergies	1	0
Type IV hypersensitivity reaction	12	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	5	0
Drug hypersensitivity	3	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	25	0
Anaphylactic shock	3	0
Anaphylactoid reaction	2	0
<i>Atopic disorders</i>		
Seasonal allergy	12	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	21	0
Cytokine release syndrome	1	0
Immune-mediated adverse reaction	1	0
Sensitisation	3	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immune system disorders SOC TOTAL	260	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	3	0
Diverticulitis	2	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	47	0
Folliculitis	1	0
Injection site cellulitis	2	0
Skin bacterial infection	1	0
Vaccination site cellulitis	1	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	1	0
<i>Candida infections</i>		
Candida infection	4	0
Oral candidiasis	1	0
Vulvovaginal candidiasis	7	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	2	0
<i>Coronavirus infections</i>		
COVID-19	46	0
COVID-19 pneumonia	1	0
Suspected COVID-19	1	0
<i>Coxiella infections</i>		
Q fever	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		
Ear infection	3	0
Labyrinthitis	2	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	8	0
Eyelid boil	1	0
Hordeolum	1	0
<i>Female reproductive tract infections</i>		
Vaginal infection	1	0
<i>Flaviviral infections</i>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
Fungal skin infection	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Herpes viral infections</i>		
Genital herpes	6	0
Herpes ophthalmic	1	0
Herpes zoster	32	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	27	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess limb	1	0
Abscess rupture	1	0
Infection	49	0
Injection site infection	1	0
Localised infection	9	0
Respiratory tract infection	1	0
Vaccination site infection	2	0
Vestibulitis	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	2	0
<i>Infectious transmissions</i>		
Secondary transmission	2	0
<i>Influenza viral infections</i>		
Influenza	152	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	3	0
Lower respiratory tract infection	14	0
Pneumonia	7	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Impetigo	2	0
Pustule	8	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	8	0
<i>Staphylococcal infections</i>		
Furuncle	2	0
<i>Tinea infections</i>		
Body tinea	2	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
<i>Upper respiratory tract infections</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Laryngitis	1	0
Nasopharyngitis	112	0
Peritonsillar abscess	1	0
Rhinitis	1	0
Sinusitis	6	0
Tonsillitis	10	0
Upper respiratory tract infection	1	0
Urinary tract infections		
Cystitis	3	0
Kidney infection	1	0
Urinary tract infection	13	0
Vascular infections		
Lymphangitis	1	0
Viral infections NEC		
Conjunctivitis viral	1	0
Gastroenteritis viral	1	0
Post viral fatigue syndrome	2	0
Sweating fever	15	0
Viral infection	1	0
Viral pharyngitis	2	0
Viral rash	4	0
Infections SOC TOTAL	682	1

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Cardiovascular injuries</i>		
Heart injury	1	0
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	5	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	7	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	4	0
Maternal exposure during breast feeding	268	0
Maternal exposure during pregnancy	122	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat oedema	2	0
Heat stroke	6	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	3	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	5	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Muscle injury	1	0
Muscle strain	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	5	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	3	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	3	0
Bite	1	0
Electric shock	3	0
Fall	13	0
Injury	1	0
Wound complication	2	0
Wound haemorrhage	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Non-site specific procedural complications</i>		
Injection related reaction	3	0
Procedural pain	1	0
<i>Overdoses NEC</i>		
Overdose	4	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Expired product administered	5	0
Inappropriate schedule of product administration	6	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Poor quality product administered	1	0
Product administered at inappropriate site	1	0
Product dose omission issue	1	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Radiation injuries</i>		
Sunburn	9	0
<i>Site specific injuries NEC</i>		
Head injury	5	0
Limb injury	10	0
<i>Skin injuries NEC</i>		
Contusion	138	0
Scar	8	0
Scratch	1	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<i>Stoma complications</i>		
Stoma site oedema	1	0
<i>Thermal burns</i>		
Thermal burn	5	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Injuries SOC TOTAL	682	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Campylobacter test positive	1	0
<i>Blood counts NEC</i>		
Blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen consumption decreased	1	0
Oxygen saturation decreased	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
Blood glucose increased	2	0
<i>Cardiac auscultatory investigations</i>		
Heart sounds	2	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram P wave abnormal	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram T wave inversion	2	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	2	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	61	0
Heart rate abnormal	4	0
Heart rate decreased	3	0
Heart rate increased	92	0
Heart rate irregular	18	0
Heart rate variability decreased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	2	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	4	0
Aspartate aminotransferase	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	5	0
Liver function test increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Visual tracking test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	30	0
Body temperature abnormal	1	0
Body temperature decreased	3	0
Body temperature fluctuation	8	0
Body temperature increased	29	0
Grip strength	1	0
Grip strength decreased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Lymph node palpable	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	6	0
Skin temperature	8	0
Temperature difference of extremities	1	0
Weight decreased	9	0
Weight increased	5	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	8	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	1	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Reproductive hormone analyses</i>		
Pregnancy test	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Troponin T increased	1	0
Troponin increased	1	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	1	0
<i>Urinalysis NEC</i>		
Blood urine present	4	0
Protein urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
Urine output decreased	1	0
<i>Urinary tract imaging procedures</i>		
Bladder scan	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	6	0
Blood pressure diastolic increased	1	0
Blood pressure increased	7	0
Blood pressure measurement	2	0
<i>Virus identification and serology</i>		
Coronavirus test	4	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	2	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Investigations SOC TOTAL	390	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	107	0
Food craving	1	0
Food refusal	1	0
Hyperphagia	3	0
Hypophagia	1	0
Increased appetite	5	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	2	0
Diabetes mellitus inadequate control	1	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Disorders of purine metabolism</i>		
Gout	8	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	4	0
Feeding disorder	13	0
Food aversion	2	0
Neonatal insufficient breast milk syndrome	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	4	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	27	0
<i>Total fluid volume increased</i>		
Fluid retention	8	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	203	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	10	0
Arthropathy	3	0
Autoimmune arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	23	0
Bone swelling	1	0
Pain in jaw	30	0
Spinal pain	3	0
<i>Bursal disorders</i>		
Bursitis	5	0
<i>Cartilage disorders</i>		
Costochondritis	6	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	1	0
Reynold's syndrome	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	1	0
<i>Joint related disorders NEC</i>		
Joint lock	3	0
Periarthritis	12	0
Rotator cuff syndrome	1	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	650	0
Joint noise	1	0
Joint stiffness	20	0
Joint swelling	24	0
Joint vibration	1	0
Joint warmth	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
<i>Muscle infections and inflammations</i>		
Myositis	4	0
<i>Muscle pains</i>		
Fibromyalgia	4	0
Myalgia	1043	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle fatigue	33	0
Muscle haemorrhage	1	0
Muscle spasms	170	0
Muscle swelling	6	0
Muscle tightness	13	0
Muscle twitching	37	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
Nuchal rigidity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	62	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mastication disorder	1	0
Mobility decreased	3	0
Muscle contracture	1	0
Musculoskeletal stiffness	164	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dupuytren's contracture	1	0
Fasciitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	223	0
Flank pain	4	0
Limb discomfort	162	0
Musculoskeletal chest pain	12	0
Musculoskeletal discomfort	6	0
Musculoskeletal pain	1	0
Neck pain	115	0
Pain in extremity	1550	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	3	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	21	0
Groin pain	5	0
Neck mass	1	0
Soft tissue swelling	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	1	0
Arthritis reactive	3	0
Axial spondyloarthritis	1	0
<i>Synovial disorders</i>		
Synovial cyst	3	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Trigger finger	2	0
Muscle & tissue disorders SOC TOTAL	4475	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	3	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
Haemangioma of skin	2	0
Skin papilloma	4	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	2	1
Cerebral infarction	1	0
Cerebrovascular accident	8	0
Haemorrhage intracranial	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	18	0
Coordination abnormal	1	0
Dysstasia	3	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	7	0
Lethargy	148	0
Loss of consciousness	93	0
Somnolence	96	0
Stupor	1	0
Syncope	469	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	2	0
Dyskinesia	5	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Hyperkinesia	1	0
Hypokinesia	4	0
Movement disorder	4	0
Psychomotor hyperactivity	1	0
<i>Eye movement disorders</i>		
IVth nerve paresis	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	28	0
Facial paralysis	18	0
Facial paresis	2	0
Facial spasm	4	0
<i>Glossopharyngeal nerve disorders</i>		
Glossopharyngeal neuralgia	1	0
<i>Headaches NEC</i>		
Cluster headache	22	0
Cold-stimulus headache	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Drug withdrawal headache	1	0
Headache	2270	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Sinus headache	27	0
Tension headache	43	0
Thunderclap headache	1	0
Vascular headache	2	0
Increased intracranial pressure disorders		
Intracranial pressure increased	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	2	0
Memory loss (excl dementia)		
Amnesia	13	0
Memory impairment	13	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	6	0
Disturbance in attention	33	0
Mental impairment	2	0
Migraine headaches		
Hemiplegic migraine	2	0
Migraine	235	0
Migraine with aura	23	0
Migraine without aura	2	0
Retinal migraine	1	0
Vestibular migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Cubital tunnel syndrome	1	0
Mononeuritis	1	0
Muscle tone abnormal		
Hypotonia	2	0
Narcolepsy and hypersomnia		
Hypersomnia	8	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurologic visual problems NEC		
Tunnel vision	4	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	1276	0
Dizziness exertional	2	0
Dizziness postural	50	0
Drooling	2	0
Head discomfort	26	0
Neurological symptom	4	0
Persistent postural-perceptual dizziness	1	0
Presyncope	99	0
Unresponsive to stimuli	7	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Olfactory nerve disorders</i>		
Anosmia	10	0
Parosmia	9	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	40	0
Formication	2	0
Hemianaesthesia	1	0
Hyperaesthesia	21	0
Hypoaesthesia	251	0
Paraesthesia	359	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	5	0
Hemiplegia	3	0
Monoparesis	8	0
Monoplegia	10	0
Paralysis	9	0
Paresis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	5	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	2	0
Febrile convulsion	3	0
Partial seizures	2	0
Psychogenic seizure	1	0
Seizure	74	0
Status epilepticus	24	0
Tonic clonic movements	2	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	25	0
Dysgeusia	89	0
Electric shock sensation	2	0
Hypogeusia	1	0
Neuralgia	29	0
Post herpetic neuralgia	2	0
Restless legs syndrome	17	0
Sensory disturbance	7	0
Sensory loss	5	0
Taste disorder	14	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	14	0
Incoherent	5	0
Slow speech	2	0
Speech disorder	6	0
<i>Spinal cord and nerve root disorders NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	6	0
<i>Tremor (excl congenital)</i>		
Tremor	144	0
<i>Trigeminal disorders</i>		
Facial neuralgia	1	0
Trigeminal neuralgia	1	0
Nervous system disorders SOC TOTAL	6348	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	21	1
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	2	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	8	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	44	2

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	7	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
null SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Flat affect	3	0
<i>Anxiety symptoms</i>		
Agitation	9	0
Anxiety	114	0
Nervousness	21	0
Stress	8	0
Tension	5	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	0
<i>Behaviour and socialisation disturbances</i>		
Paranoia	4	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	25	0
<i>Confusion and disorientation</i>		
Confusional state	62	0
Disorientation	26	0
<i>Deliria</i>		
Delirium	12	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	34	0
Depression suicidal	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Dissociation	5	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	115	0
Middle insomnia	6	0
Terminal insomnia	7	0
<i>Dyssomnias</i>		
Poor quality sleep	27	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	7	0
Emotional disorder	10	0
Emotional distress	7	0
Euphoric mood	7	0
Irritability	23	0
Mood altered	6	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Fear of death	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Fear of injection	7	0
Phobia	1	0
Fluctuating mood symptoms		
Mood swings	9	0
Hallucinations (excl sleep-related)		
Hallucination	37	0
Hallucination, auditory	2	0
Hallucination, visual	1	0
Increased physical activity levels		
Restlessness	22	0
Mental disorders NEC		
Mental disorder	3	0
Mood alterations with depressive symptoms		
Depressed mood	30	0
Feeling of despair	2	0
Tearfulness	2	0
Mood alterations with manic symptoms		
Mania	3	0
Mood disorders NEC		
Apathy	4	0
Listless	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	1	0
Orgasmic disorders and disturbances		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
Panic attacks and disorders		
Panic attack	27	0
Panic reaction	5	0
Parasomnias		
Abnormal dreams	16	0
Nightmare	19	0
Sleep terror	1	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	2	0
Derealisation	1	0
Psychiatric elimination disorders		
Enuresis	6	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	1	0
Sexual desire disorders		
Libido decreased	3	0
Libido increased	1	0
Loss of libido	2	0
Sleep disorders NEC		
Sleep disorder	13	0
Somatic symptom disorders		
Conversion disorder	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Habit cough	4	0
Speech and language usage disturbances		
Disorganised speech	1	0
Speech articulation and rhythm disturbances		
Dysphemia	2	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	1	0
Head banging	1	0
Stress disorders		
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	4	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	815	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	3	0
Dysuria	5	0
Incontinence	2	0
Micturition urgency	2	0
Pollakiuria	12	0
Urethral pain	1	0
Urinary incontinence	5	0
Urinary retention	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Urinary bladder haemorrhage	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	3	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	8	0
Haematuria	1	0
Urine abnormality	3	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	5	0
Renal pain	26	0
Renal & urinary disorders SOC TOTAL	85	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	2	0
<i>Breast disorders NEC</i>		
Breast enlargement	2	0
Breast mass	7	0
Fibrocystic breast disease	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	45	0
Breast swelling	5	0
Breast tenderness	3	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	5	0
Organic erectile dysfunction	3	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Lactation disorder	1	0
Lactation puerperal increased	1	0
Suppressed lactation	2	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	6	0
Premature menopause	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	7	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	183	0
Intermenstrual bleeding	103	0
Menstrual discomfort	1	0
Menstrual disorder	174	0
Menstruation irregular	285	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	7	0
Premenstrual syndrome	8	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	45	0
Hypomenorrhoea	61	0
Menstruation delayed	361	0
Oligomenorrhoea	12	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	472	0
Menometrorrhagia	4	0
Polymenorrhoea	66	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
Polycystic ovaries	2	0
<i>Ovarian and fallopian tube disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Ovulation pain	9	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	5	0
Pelvic haemorrhage	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	1	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	2	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	8	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	5	0
Testicular swelling	2	0
<i>Uterine disorders NEC</i>		
Endometriosis	6	0
Uterine haemorrhage	5	0
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	6	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	2	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	132	0
Vulval haemorrhage	5	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	7	0
Vulvovaginal discomfort	1	0
Vulvovaginal pain	2	0
Reproductive & breast disorders SOC TOTAL	2102	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	280	0
Dyspnoea exertional	3	0
Hyperventilation	2	0
Hypopnoea	6	0
Hypoventilation	1	0
Respiration abnormal	6	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	18	0
Wheezing	30	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	150	0
Haemoptysis	1	0
Productive cough	14	0
Sputum discoloured	2	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	1	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	12	0
Pulmonary haemorrhage	1	0
Pulmonary pain	7	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	18	0
<i>Nasal disorders NEC</i>		
Epistaxis	65	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	4	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	2	0
Pharyngeal swelling	33	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	5	0
<i>Pleural infections and inflammations</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pleurisy	2	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	14	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	5	0
Catarrh	1	0
Choking	1	0
Dry throat	10	0
Dysphonia	6	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discomfort	3	0
Oropharyngeal blistering	1	0
Oropharyngeal discomfort	4	0
Oropharyngeal pain	197	0
Paranasal sinus discomfort	5	0
Rhinalgia	1	0
Rhinorrhoea	48	0
Sinus pain	22	0
Sneezing	10	0
Throat irritation	18	0
Throat tightness	25	0
Upper-airway cough syndrome	1	0
Yawning	1	0
Respiratory disorders SOC TOTAL	1066	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	14	0
<i>Alopecias</i>		
Alopecia	17	0
Alopecia areata	3	0
Alopecia totalis	1	0
<i>Angioedemas</i>		
Angioedema	16	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	112	0
Hyperhidrosis	317	0
Miliaria	42	0
Night sweats	63	0
<i>Bullous conditions</i>		
Blister	30	0
Blister rupture	1	0
Dermatitis bullous	1	0
Erythema multiforme	10	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	44	0
Pain of skin	38	0
Papule	14	0
Scab	2	0
Scar pain	2	0
Sensitive skin	47	0
Skin burning sensation	27	0
Skin discolouration	14	0
Skin induration	5	0
Skin lesion	18	0
Skin reaction	67	0
Skin sensitisation	6	0
Skin swelling	11	0
Skin tightness	4	0
Skin warm	125	0
Yellow skin	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	15	0
Dermatitis allergic	63	0
Dermatitis atopic	5	0
Dermatitis contact	3	0
Dyshidrotic eczema	8	0
Eczema	23	0
Eczema nummular	1	0
Neurodermatitis	1	0
Skin irritation	14	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	628	0
<i>Exfoliative conditions</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	1	0
Skin exfoliation	6	0
Hyperpigmentation disorders		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
Nail and nail bed conditions (excl infections and infestations)		
Onychoclasia	1	0
Panniculitides		
Erythema nodosum	1	0
Papulosquamous conditions		
Lichen planus	2	0
Pityriasis rosea	2	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	11	0
Pilar disorders NEC		
Piloerection	6	0
Pruritus NEC		
Itching scar	2	0
Pruritus	1402	0
Psoriatic conditions		
Guttate psoriasis	1	0
Psoriasis	12	0
Purpura and related conditions		
Petechiae	13	0
Purpura	6	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	1613	0
Rash erythematous	648	0
Rash macular	96	0
Rash maculo-papular	1	0
Rash morbilliform	4	0
Rash papular	113	0
Rash pruritic	375	0
Rash vesicular	4	0
Rosaceas		
Rosacea	2	0
Scaly conditions		
Pityriasis	1	0
Sebaceous gland disorders		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	3	0
Skin mass	4	0
Skin and subcutaneous tissue ulcerations		
Skin ulcer	2	0
Skin cysts and polyps		
Dermal cyst	3	0
Skin haemorrhages		
Skin haemorrhage	1	0
Skin hypoplasias and atrophies		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin atrophy	2	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	2	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	223	0
Urticaria cholinergic	1	0
Urticaria chronic	1	0
Skin disorders SOC TOTAL	6395	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menopause	3	0
<i>Disability issues</i>		
Bedridden	1	0
Immobile	1	0
Impaired driving ability	1	0
Sight disability	1	0
<i>Employment issues</i>		
Retirement	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	4	0
Social circumstances SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	1	0
<i>Immunisations</i>		
COVID-19 immunisation	10	0
Immunisation	9	0
<i>Joint therapeutic procedures</i>		
Joint stabilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	2	0
<i>Therapeutic procedures NEC</i>		
Bed rest	2	0
Botulinum toxin injection	1	0
Hospitalisation	1	0
Injection	10	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	41	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive urgency	1	0
<i>Arterial infections and inflammations</i>		
Giant cell arteritis	1	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Neurogenic shock	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	4	0
Haemorrhage	109	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	4	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	2	0
Embolism venous	1	0
Thrombosis	46	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arteriosclerosis	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	3	0
Vasodilatation	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	2	0
Deep vein thrombosis	11	0
Thrombophlebitis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	4	0
Flushing	18	0
Hot flush	121	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	27	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	47	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	43	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	46	0
Orthostatic hypotension	3	0
<i>Vasculitides NEC</i>		

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vasculitis	1	0
Vascular disorders SOC TOTAL	513	0
TOTAL REACTIONS FOR DRUG	41274	14
TOTAL REPORTS	13325	
TOTAL FATAL OUTCOME REPORTS		14