

COVID-19 Moderna vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 15/12/21 for 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: 20-Dec-2021

Data Lock Date: 15-Dec-2021 18:32:39

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	4	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	3	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	224	0
Lymphadenitis	18	0
Lymphadenopathy	1276	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	2	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	6	0
Thrombocytopenia	23	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	1567	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	2	0
Bundle branch block left	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	8	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	818	0
<i>Cardiomyopathies</i>		
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Coronary artery occlusion	1	0
Coronary artery stenosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	3	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	1	0
Angina pectoris	35	0
Myocardial infarction	12	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	2	0
Left ventricular dysfunction	2	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
Myocardial oedema	1	0
<i>Noninfectious myocarditis</i>		
Hypersensitivity myocarditis	1	0
Myocarditis	120	0
<i>Noninfectious pericarditis</i>		
Pericarditis	69	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	19	0
Bradycardia	9	0
Cardiac fibrillation	1	0
Cardiac flutter	70	0
Extrasystoles	24	0
Tachycardia	261	0
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	17	0
Atrial flutter	8	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Sinus tachycardia	5	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	9	1
Ventricular extrasystoles	1	0
Ventricular tachycardia	3	0
Cardiac disorders SOC TOTAL	1526	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	2	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	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>Musculoskeletal disorders congenital NEC</i>		
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	7	0
Ear discomfort	4	0
Ear disorder	3	0
Ear inflammation	1	0
Ear pain	186	0
Ear swelling	4	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing losses</i>		
Deafness	28	0
Deafness transitory	1	0
Deafness unilateral	4	0
Hypoacusis	23	0
Sudden hearing loss	9	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	13	0
Tinnitus	247	0
Vertigo	206	0
Vertigo labyrinthine	1	0
Vertigo positional	9	0
Ear disorders SOC TOTAL	758	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	3	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	6	0
Ovulation delayed	10	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Goitre	5	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
Endocrine disorders SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	2	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	1	0
Vitreous detachment	1	0
Vitreous floaters	10	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	6	0
<i>Eyelid movement disorders</i>		
Blepharospasm	23	0
Eyelid ptosis	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Uveitis	7	0
<i>Lacrimation disorders</i>		
Dry eye	24	0
Lacrimation increased	11	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid irritation	1	0
Eyelid rash	1	0
Swelling of eyelid	14	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	0
Eye pain	223	0
Eye swelling	82	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	2	0
Periorbital swelling	15	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye discharge	1	0
Eye inflammation	4	0
Eye irritation	13	0
Eye pruritus	26	0
Ocular hyperaemia	27	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	14	0
Foreign body sensation in eyes	5	0
Hypoaesthesia eye	4	0
Photophobia	93	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>		

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Eye disorders Eye disorders cont'd		
Orbital myositis	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	2	0
<i>Pupil disorders</i>		
Mydriasis	3	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Astigmatism	3	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	4	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	4	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Exophthalmos	1	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Diplopia	22	0
Halo vision	3	0
Metamorphopsia	4	0
Photopsia	23	0
Vision blurred	210	0
<i>Visual field disorders</i>		
Visual field defect	3	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	20	0
Blindness transient	4	0
Blindness unilateral	1	0
Visual acuity reduced	2	0
Visual impairment	37	0
Eye disorders SOC TOTAL	989	0

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Reaction Name	Total	Fatal
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	5	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	3	0
Colitis ulcerative	5	0
Crohn's disease	8	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teething	2	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental paraesthesia	3	0
Hyperaesthesia teeth	5	0
Toothache	18	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	761	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	88	0
Epigastric discomfort	1	0
Eructation	9	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	8	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	45	0
Flatulence	24	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	5	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	230	0
Abdominal pain lower	19	0
Abdominal pain upper	564	0
Abdominal rigidity	3	0
Abdominal tenderness	2	0
Gastrointestinal pain	21	0
Oesophageal pain	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	30	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	27	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Gastric disorder	1	0
Gastrointestinal disorder	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	103	0
Anal incontinence	3	0
Breath odour	6	0
Dysphagia	24	0
Odynophagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	5	0
Irritable bowel syndrome	10	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	2	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	2	0
Gingival pain	11	0
Gingival swelling	5	0
Noninfective gingivitis	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	10	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	4	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	13	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	3171	0
Regurgitation	1	0
Retching	18	0
Vomiting	1177	0
Vomiting projectile	8	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	3	0
Haematochezia	6	0
Melaena	1	0
Upper gastrointestinal haemorrhage	5	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	73	0
Lip dry	6	0
Saliva altered	2	0
Salivary hypersecretion	7	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
Cheilitis	2	0
Enlarged uvula	1	0
Lip blister	3	0
Lip disorder	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	4	0
Oral blood blister	4	0
<i>Oral soft tissue signs and symptoms</i>		
Coating in mouth	2	0
Hypoaesthesia oral	63	0
Lip discolouration	1	0
Lip pain	6	0
Lip pruritus	1	0
Oral discomfort	7	0
Oral mucosal eruption	2	0
Oral mucosal roughening	1	0
Oral pain	23	0
Oral pruritus	1	0
Paraesthesia oral	100	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	125	0
Mouth swelling	13	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	3	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	2	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	3	0
Lip ulceration	4	0
Mouth ulceration	66	0
Stomatitis	4	0
<i>Tongue disorders</i>		

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Gastrointestinal disorders		
Glossitis	5	0
Tongue disorder	5	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	21	0
Stiff tongue	1	0
Swollen tongue	61	0
Tongue blistering	2	0
Tongue coated	3	0
Tongue discolouration	3	0
Tongue discomfort	5	0
Tongue dry	2	0
Tongue movement disturbance	1	0
Tongue oedema	2	0
Tongue pruritus	1	0
<i>Tooth missing</i>		
Tooth loss	1	0
Gastrointestinal disorders SOC TOTAL	7171	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site lymphadenopathy	1	0
Administration site pain	2	0
Administration site reaction	2	0
Administration site warmth	1	0
Puncture site bruise	5	0
Puncture site pain	3	0
Vessel puncture site bruise	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	7	0
Application site joint erythema	1	0
Application site pain	2	0
Application site pruritus	10	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	403	0
Chronic fatigue syndrome	6	0
Decreased activity	1	0
Fatigue	4170	0
Malaise	767	0
<i>Body temperature altered</i>		
Hypothermia	3	0
Temperature regulation disorder	2	0
<i>Death and sudden death</i>		
Death	10	10
Sudden death	2	2
<i>Febrile disorders</i>		
Pyrexia	4539	1
<i>Feelings and sensations NEC</i>		
Chills	2793	0
Feeling abnormal	343	0
Feeling cold	235	0
Feeling drunk	12	0
Feeling hot	272	0
Feeling jittery	10	0
Feeling of body temperature change	75	0
Hangover	18	0
Hunger	16	0
Sensation of blood flow	1	0
Sensation of foreign body	5	0
Temperature intolerance	19	0
Thirst	91	0
<i>Gait disturbances</i>		

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General disorders General disorders cont'd		
Gait disturbance	22	0
Gait inability	9	0
Loss of control of legs	3	0
General signs and symptoms NEC		
Condition aggravated	19	0
Crying	28	0
Discharge	3	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	5	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	435	0
Induration	10	0
Influenza like illness	570	0
Irritability postvaccinal	1	0
Local reaction	24	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	1700	0
Screaming	4	0
Secretion discharge	2	0
Swelling	908	0
Swelling face	120	0
Implant and catheter site reactions		
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	126	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	3	0
Infusion site mass	1	0
Infusion site pain	4	0
Infusion site pruritus	2	0
Infusion site urticaria	3	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	5	0
Injection site bruising	13	0
Injection site cyst	1	0
Injection site discolouration	1	0
Injection site erythema	156	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	5	0
Injection site indentation	2	0
Injection site inflammation	10	0
Injection site irritation	3	0

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General disorders General disorders cont'd		
Injection site joint erythema	4	0
Injection site joint pain	1	0
Injection site mass	168	0
Injection site oedema	2	0
Injection site pain	601	0
Injection site paraesthesia	1	0
Injection site plaque	1	0
Injection site pruritus	101	0
Injection site rash	176	0
Injection site reaction	17	0
Injection site swelling	81	0
Injection site urticaria	49	0
Injection site vesicles	2	0
Injection site warmth	78	0
Interactions		
Alcohol interaction	1	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	6	0
Mass	22	0
Nodule	6	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema mucosal	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	5	0
Localised oedema	5	0
Oedema	8	0
Oedema peripheral	11	0
Pain and discomfort NEC		
Axillary pain	594	0
Chest discomfort	270	0
Chest pain	877	0
Discomfort	94	0
Facial pain	26	0
Inflammatory pain	3	0
Non-cardiac chest pain	2	0
Pain	1841	0
Tenderness	153	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	71	0
Adverse event	1	0
Adverse reaction	4	0
Drug ineffective	11	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	5	0
Therapeutic product effect decreased	1	0

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General disorders General disorders cont'd		
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	2	0
Ulcers NEC		
Ulcer	4	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	6	0
Vaccination site bruising	20	0
Vaccination site discolouration	2	0
Vaccination site discomfort	6	0
Vaccination site eczema	1	0
Vaccination site erythema	277	0
Vaccination site haemorrhage	3	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	17	0
Vaccination site inflammation	10	0
Vaccination site irritation	1	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	68	0
Vaccination site movement impairment	14	0
Vaccination site oedema	1	0
Vaccination site pain	301	0
Vaccination site papule	2	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	63	0
Vaccination site rash	134	0
Vaccination site reaction	5	0
Vaccination site scar	1	0
Vaccination site swelling	172	0
Vaccination site urticaria	12	0
Vaccination site vesicles	1	0
Vaccination site warmth	123	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	7	0
General disorders SOC TOTAL	24655	14

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 20-Dec-2021

Data Lock Date: 15-Dec-2021 18:32:39

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	0
<i>Cholestasis and jaundice</i>		
Jaundice	5	0
Jaundice cholestatic	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	7	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic steatosis	1	0
Hepatitis	1	0
Immune-mediated hepatitis	1	0
Hepatic disorders SOC TOTAL	28	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	2	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to animal	1	0
Allergy to metals	1	0
Hypersensitivity	250	0
Infusion related hypersensitivity reaction	12	0
Multiple allergies	3	0
Serum sickness	1	0
Type IV hypersensitivity reaction	13	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	2	0
Allergy to vaccine	12	0
Drug hypersensitivity	10	0
Food allergy	1	0
Milk allergy	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	52	0
Anaphylactic shock	6	0
Anaphylactoid reaction	3	0
<i>Atopic disorders</i>		
Seasonal allergy	15	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	2	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	39	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
Sensitisation	4	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	442	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	5	0
Diverticulitis	2	0
Dysentery	1	0
Gastroenteritis	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Bacterial infection	2	0
Cellulitis	66	0
Folliculitis	1	0
Injection site cellulitis	2	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	4	0
<i>Candida infections</i>		
Candida infection	5	0
Oral candidiasis	2	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	93	0
COVID-19 pneumonia	5	0
Suspected COVID-19	3	0
<i>Coxiella infections</i>		
Q fever	5	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	1	0
Cytomegalovirus infection reactivation	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	2	0
Sialoadenitis	1	0
Tooth abscess	1	0
Tooth infection	1	0
<i>Ear infections</i>		
Ear infection	5	0
Labyrinthitis	6	0
Otitis externa	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	10	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Eye infection	2	0
Eyelid boil	1	0
Hordeolum	2	0
Female reproductive tract infections		
Vaginal infection	1	0
Flaviviral infections		
Dengue fever	2	0
Encephalitis Japanese B	1	0
Fungal infections NEC		
Fungal infection	3	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
Fusobacterium infections		
Necrotising ulcerative gingivostomatitis	1	0
Herpes viral infections		
Eczema herpeticum	2	0
Genital herpes	10	0
Herpes ophthalmic	1	0
Herpes simplex	3	0
Herpes zoster	65	0
Herpes zoster oticus	1	0
Ophthalmic herpes simplex	1	0
Oral herpes	62	0
Varicella	3	0
Infections NEC		
Abscess limb	1	0
Abscess rupture	1	0
Infection	72	0
Injection site infection	1	0
Localised infection	16	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	4	0
Vestibulitis	1	0
Wound infection	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	411	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	4	0
Lower respiratory tract infection	40	1
Pneumonia	11	1
Male reproductive tract infections		
Epididymitis	1	0
Orchitis	2	0
Mumps viral infections		
Mumps	1	0
Nematode infections		

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 20-Dec-2021

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Enterobiasis	1	0
<i>Rabies viral infections</i>		
Rabies	1	1
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubella viral infections</i>		
Rubella	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Intestinal sepsis	1	0
Sepsis	2	0
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Eczema infected	1	0
Impetigo	3	0
Pustule	9	0
Pyoderma	1	0
Rash pustular	2	0
Skin infection	10	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	8	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Laryngitis	2	0
Nasopharyngitis	234	0
Peritonsillar abscess	1	0
Pharyngitis	4	0
Rhinitis	5	0
Sinusitis	19	0
Tonsillitis	11	0
Upper respiratory tract infection	1	0
<i>Urinary tract infections</i>		
Cystitis	7	0
Kidney infection	3	0
Urinary tract infection	25	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Gastroenteritis viral	2	0
Meningitis viral	1	0
Post viral fatigue syndrome	5	0
Sweating fever	40	0
Vestibular neuronitis	2	0
Viral infection	4	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral labyrinthitis	1	0
Viral pharyngitis	4	0
Viral rash	7	0
Infections SOC TOTAL	1427	3

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

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>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	6	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	13	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	16	0
Foetal exposure during pregnancy	7	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	390	0
Maternal exposure during pregnancy	192	0
Maternal exposure timing unspecified	1	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat illness	1	0
Heat oedema	4	0
Heat stroke	7	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	8	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	8	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	3	0
Ligament sprain	1	0
Muscle injury	1	0
Muscle strain	2	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	14	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	4	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<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	5	0
Fall	27	0
Inflammation of wound	2	0
Injury	3	0
Multiple injuries	1	0
Nervous system injury	1	0
Wound complication	5	0
Wound haemorrhage	1	0
<i>Non-site specific procedural complications</i>		
Injection related reaction	19	0
Post procedural erythema	1	0
Procedural pain	1	0
<i>Occupational exposures</i>		
Occupational exposure to toxic agent	1	0
<i>Off label uses</i>		
Off label use	15	0
<i>Overdoses NEC</i>		
Overdose	6	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
<i>Poisoning and toxicity</i>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	62	0
Expired product administered	28	0
Extra dose administered	2	0
Inappropriate schedule of product administration	29	0
Incorrect dose administered	9	0
Incorrect route of product administration	2	0
Poor quality product administered	1	0
Product administered at inappropriate site	3	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	1	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Product prescribing errors and issues</i>		
Contraindicated product prescribed	1	0
<i>Radiation injuries</i>		
Sunburn	13	0
<i>Site specific injuries NEC</i>		
Back injury	1	0
Head injury	7	0
Limb injury	23	0
<i>Skin injuries NEC</i>		
Contusion	245	0
Scar	9	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Scratch	2	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
<i>Skull fractures, facial bone fractures and dislocations</i>		
Jaw fracture	1	0
<i>Spinal cord injuries NEC</i>		
Spinal cord injury cervical	1	0
<i>Stoma complications</i>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<i>Thermal burns</i>		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	12	0
Thermal burns of eye	3	0
<i>Thoracic cage fractures and dislocations</i>		
Sternal fracture	1	0
<i>Vaccination related complications</i>		
Vaccination complication	12	0
Injuries SOC TOTAL	1275	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

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>		
Full blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen consumption decreased	1	0
Oxygen saturation	2	0
Oxygen saturation decreased	11	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	1	0
Blood glucose increased	3	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
Heart sounds	3	0
<i>Cardiac function diagnostic procedures</i>		
Ejection fraction decreased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	1	0
<i>Cholesterol analyses</i>		
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time abnormal	1	0
Fibrin D dimer increased	1	0
<i>ECG investigations</i>		
Electrocardiogram	1	0
Electrocardiogram P wave abnormal	1	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	1	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	1	0
Electrocardiogram change	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	9	0
<i>Fertility analyses</i>		
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
X-ray with contrast upper gastrointestinal tract	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	152	0
Heart rate abnormal	13	0
Heart rate decreased	10	0
Heart rate increased	256	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate irregular	44	0
Heart rate variability decreased	1	0
Investigations NEC		
Blood test abnormal	3	0
Liver function analyses		
Alanine aminotransferase increased	5	0
Aspartate aminotransferase	2	0
Bile output	1	0
Blood bilirubin increased	1	0
Liver function test abnormal	6	0
Liver function test increased	1	0
Transaminases increased	1	0
Mineral and electrolyte analyses		
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone scan	1	0
Musculoskeletal and soft tissue tests NEC		
Tender joint count	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Sensory level	1	0
Ophthalmic function diagnostic procedures		
Visual tracking test	1	0
Visual tracking test abnormal	1	0
Physical examination procedures and organ system status		
Body temperature	70	0
Body temperature abnormal	5	0
Body temperature decreased	6	0
Body temperature fluctuation	16	0
Body temperature increased	76	0
Breath sounds	1	0
Grip strength	1	0
Grip strength decreased	2	0
Head lag	3	0
Lymph node palpable	3	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	3	0
Respiratory rate decreased	5	0
Respiratory rate increased	7	0
Skin temperature	13	0
Temperature difference of extremities	3	0
Weight decreased	15	0
Weight increased	9	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count decreased	7	0
Protein analyses NEC		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
C-reactive protein increased	6	0
Red blood cell analyses		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
Renal function analyses		
Blood creatinine increased	1	0
Reproductive hormone analyses		
Pregnancy test	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	3	0
Therapeutic drug monitoring analyses		
Analgesic drug level	5	0
Thyroid analyses		
Tri-iodothyronine decreased	1	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase increased	1	0
Urinalysis NEC		
Blood urine	2	0
Blood urine present	15	0
Protein urine	1	0
pH urine	1	0
Urinary tract function analyses NEC		
Urine output	5	0
Urine output decreased	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	1	0
Blood pressure decreased	9	0
Blood pressure diastolic increased	1	0
Blood pressure increased	23	0
Blood pressure measurement	5	0
Blood pressure normal	1	0
Virus identification and serology		
Coronavirus test	4	0
Influenza A virus test	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	1	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	4	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	4	0
Vitamin analyses		
Blood folate decreased	1	0
White blood cell analyses		

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Lymphocyte count	1	0
Neutrophil count	1	0
White blood cell count	1	0
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	936	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	269	0
Food craving	2	0
Food refusal	2	0
Hyperphagia	5	0
Hypophagia	1	0
Increased appetite	7	0
Salt craving	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	3	0
Diabetes mellitus inadequate control	4	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	12	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	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	2	0
Gluten sensitivity	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Abnormal weight gain	6	0
Feeding disorder	37	0
Food aversion	4	0
Neonatal insufficient breast milk syndrome	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	7	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	10	0
<i>Potassium imbalance</i>		
Hypokalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	66	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	465	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	34	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	7	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
<i>Bone disorders NEC</i>		
Jaw cyst	1	0
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	59	0
Bone swelling	1	0
Pain in jaw	68	0
Spinal pain	12	0
<i>Bursal disorders</i>		
Bursitis	14	0
<i>Cartilage disorders</i>		
Costochondritis	13	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	0
Reynold's syndrome	2	0
<i>Extremity deformities</i>		
Hand deformity	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Joint lock	5	0
Periarthritis	26	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	1656	0
Joint noise	3	0
Joint stiffness	49	0
Joint swelling	49	0
Joint vibration	1	0
Joint warmth	4	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Myositis	6	0
<i>Muscle pains</i>		
Fibromyalgia	15	0
Myalgia	2219	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	2	0
Muscle fatigue	71	0
Muscle haemorrhage	1	0
Muscle spasms	346	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle swelling	11	0
Muscle tightness	21	0
Muscle twitching	62	0
Myosclerosis	1	0
Muscle tone abnormalities		
Muscle rigidity	3	0
Nuchal rigidity	4	0
Trismus	5	0
Muscle weakness conditions		
Muscular weakness	141	0
Musculoskeletal and connective tissue conditions NEC		
Growth retardation	1	0
Mastication disorder	2	0
Mobility decreased	12	0
Muscle contracture	1	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	323	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dupuytren's contracture	1	0
Fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	501	0
Flank pain	15	0
Limb discomfort	279	0
Musculoskeletal chest pain	38	0
Musculoskeletal discomfort	12	0
Musculoskeletal pain	14	0
Neck pain	291	0
Pain in extremity	2811	0
Sacral pain	1	0
Myopathies		
Rhabdomyolysis	1	0
Osteoarthropathies		
Osteoarthritis	4	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	7	0
Soft tissue disorders NEC		
Axillary mass	39	0
Groin pain	20	0
Neck mass	8	0
Soft tissue swelling	1	0
Spondyloarthropathies		
Ankylosing spondylitis	2	0
Arthritis reactive	8	0
Axial spondyloarthritis	1	0
Synovial disorders		
Synovial cyst	4	0
Tendon disorders		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Tendon pain	2	0
Tendonitis	1	0
Trigger finger	3	0
Trunk deformities		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	9341	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage III	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	3	0
<i>Leukaemias NEC</i>		
Leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	7	0
<i>Mediastinal neoplasms malignancy unspecified NEC</i>		
Good syndrome	1	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	1	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	3	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	2	0
Neoplasms SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	7	0
<i>Autonomic nervous system disorders</i>		
Orthostatic intolerance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	2	1
Cerebral infarction	1	0
Cerebrovascular accident	18	1
Haemorrhage intracranial	1	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	1	0
Subarachnoid haemorrhage	4	0
<i>Central nervous system inflammatory disorders NEC</i>		
Central nervous system inflammation	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	3	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	57	0
Coordination abnormal	2	0
Dysstasia	7	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	3	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	10	0
Lethargy	351	0
Loss of consciousness	192	0
Somnolence	184	0
Stupor	1	0
Syncope	825	0
<i>Disturbances in sleep phase rhythm</i>		
Delayed sleep phase	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Clumsiness	4	0
Dyskinesia	8	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	9	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Motor dysfunction	2	0
Movement disorder	11	0
Psychomotor hyperactivity	1	0
Dystonias		
Dystonia	1	0
Eye movement disorders		
IVth nerve paresis	1	0
Facial cranial nerve disorders		
Bell's palsy	54	0
Facial paralysis	29	0
Facial paresis	8	0
Facial spasm	6	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	3	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cluster headache	41	0
Cold-stimulus headache	8	0
Drug withdrawal headache	2	0
Headache	5390	0
New daily persistent headache	1	0
Occipital neuralgia	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	69	0
Tension headache	108	0
Thunderclap headache	1	0
Vascular headache	2	0
Hydrocephalic conditions		
Hydrocephalus	1	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	3	0
Lumbar spinal cord and nerve root disorders		
Sciatica	7	0
Memory loss (excl dementia)		
Amnesia	31	0
Memory impairment	21	0
Transient global amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	14	0
Disturbance in attention	59	0
Mental impairment	8	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	4	0
Migraine	546	0
Migraine with aura	34	0
Migraine without aura	2	0
Retinal migraine	4	0
Typical aura without headache	1	0
Vestibular migraine	2	0
Mononeuropathies		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Carpal tunnel syndrome	2	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	2	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	1	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	1	0
Muscle tone abnormal		
Drop attacks	1	0
Hypotonia	10	0
Stiff leg syndrome	4	0
Myelitis (incl infective)		
Myelitis transverse	2	0
Narcolepsy and hypersomnia		
Hypersomnia	16	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Tunnel vision	8	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	2317	0
Dizziness exertional	5	0
Dizziness postural	128	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	48	0
Neurological symptom	5	0
Persistent postural-perceptual dizziness	2	0
Presyncope	188	0
Tongue biting	1	0
Unresponsive to stimuli	11	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	3	0
Olfactory nerve disorders		
Anosmia	29	0
Parosmia	28	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	3	0
Burning sensation	79	0
Dysaesthesia	1	0
Formication	5	0
Hemianaesthesia	2	0
Hyperaesthesia	37	0
Hypoaesthesia	453	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Paraesthesia	642	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	4	0
Hemiplegia	5	0
Monoparesis	13	0
Monoplegia	18	0
Paralysis	20	0
Paresis	2	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	6	0
Reduced facial expression	1	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	1	0
Neuralgic amyotrophy	1	0
Neuritis	1	0
Neuropathy peripheral	7	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	17	0
Febrile convulsion	3	0
Partial seizures	4	0
Psychogenic seizure	1	0
Seizure	135	0
Seizure anoxic	1	0
Status epilepticus	28	0
Tonic clonic movements	3	0
Tonic convulsion	4	0
<i>Sensory abnormalities NEC</i>		
Ageusia	63	0
Allodynia	1	0
Aura	1	0
Complex regional pain syndrome	1	0
Dysgeusia	163	0
Electric shock sensation	8	0
Hypogeusia	1	0
Neuralgia	75	0
Post herpetic neuralgia	2	0
Restless legs syndrome	31	0
Sensory disturbance	14	0
Sensory loss	21	0
Taste disorder	31	0
Vibratory sense increased	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	3	0
<i>Speech and language abnormalities</i>		
Dysarthria	23	0
Incoherent	8	0
Slow speech	4	0
Speech disorder	11	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
Radiculopathy	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	9	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Head titubation	2	0
Tremor	441	0
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	3	0
Nervous system disorders SOC TOTAL	13449	2

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	42	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	3	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	3	0
<i>Maternal complications of labour NEC</i>		
Uterine atony	1	0
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
Pregnancy conditions SOC TOTAL	68	0

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device expulsion	1	0
Device leakage	1	0
<i>Device malfunction events NEC</i>		
Thrombosis in device	1	0
<i>Manufacturing materials issues</i>		
Manufacturing materials issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	8	0
Suspected product contamination	1	0
<i>Product label issues</i>		
Product label issue	1	0
<i>Product physical issues</i>		
Product after taste	1	0
Product taste abnormal	1	0
<i>Product quality issues NEC</i>		
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<i>Product supply and availability issues</i>		
Product availability issue	2	0
null SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Flat affect	4	0
Inappropriate affect	2	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	18	0
Anxiety	184	0
Nervousness	31	0
Stress	15	0
Tension	8	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Disinhibition	1	0
Paranoia	6	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	33	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	131	0
Disorientation	58	0
<i>Deliria</i>		
Delirium	35	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	1	0
<i>Delusional symptoms</i>		
Delusion	2	0
Delusion of parasitosis	1	0
<i>Depressive disorders</i>		
Depression	64	0
Depression suicidal	4	0
Major depression	2	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	12	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	4	0
Insomnia	270	0
Middle insomnia	12	0
Terminal insomnia	12	0
<i>Dyssomnias</i>		
Poor quality sleep	56	0
<i>Eating disorders NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Binge eating	1	0
Emotional and mood disturbances NEC		
Anger	10	0
Emotional disorder	16	0
Emotional distress	8	0
Emotional poverty	1	0
Euphoric mood	10	0
Frustration tolerance decreased	1	0
Irritability	39	0
Mood altered	12	0
Factitious disorders		
Factitious disorder	1	0
Fear symptoms and phobic disorders (incl social phobia)		
Fear	2	0
Fear of death	1	0
Fear of eating	1	0
Fear of injection	6	0
Paruresis	1	0
Phobia	1	0
Phonophobia	1	0
Fluctuating mood symptoms		
Mood swings	12	0
Hallucinations (excl sleep-related)		
Hallucination	75	0
Hallucination, auditory	4	0
Hallucination, tactile	1	0
Hallucination, visual	1	0
Somatic hallucination	1	0
Increased physical activity levels		
Restlessness	42	0
Mental disorders NEC		
Mental disorder	4	0
Mood alterations with depressive symptoms		
Depressed mood	74	0
Feeling of despair	3	0
Tearfulness	5	0
Mood alterations with manic symptoms		
Mania	4	0
Mood disorders NEC		
Apathy	7	0
Listless	6	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		
Limited symptom panic attack	1	0
Panic attack	42	0
Panic reaction	8	0
Parasomnias		
Abnormal dreams	30	0
Nightmare	35	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	4	0
Somnambulism	1	0
Perception disturbances NEC		
Autoscopy	3	0
Derealisation	2	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	12	0
Psychiatric symptoms NEC		
Hypervigilance	1	0
Psychiatric symptom	1	0
Psychological trauma	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	2	0
Sexual desire disorders		
Libido decreased	5	0
Libido increased	1	0
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	49	0
Somatic symptom disorders		
Conversion disorder	4	0
Habit cough	4	0
Speech and language usage disturbances		
Disorganised speech	1	0
Speech articulation and rhythm disturbances		
Dysphemia	3	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	2	0
Head banging	2	0
Stress disorders		
Acute stress disorder	1	0
Substance related and addictive disorders		
Alcoholism	1	0
Suicidal and self-injurious behaviour		
Completed suicide	1	1
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	13	0
Suicide attempt	1	0
Thinking disturbances		
Bradyphrenia	3	0
Intrusive thoughts	1	0
Tachyphrenia	2	0
Thinking abnormal	4	0
Thought blocking	1	0
Psychiatric disorders SOC TOTAL	1589	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	1	0
Bladder pain	5	0
Dysuria	7	0
Incontinence	9	0
Micturition urgency	9	0
Pollakiuria	29	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	9	0
Urinary retention	2	0
Urinary straining	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	1	0
<i>Genitourinary tract infections and inflammations NEC</i>		
Urinary tract inflammation	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
IgA nephropathy	2	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	4	0
Oliguria	1	0
Renal impairment	1	0
<i>Urinary abnormalities</i>		
Chromaturia	16	0
Haematuria	3	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	6	0
Renal pain	60	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	185	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	3	0
<i>Breast disorders NEC</i>		
Breast enlargement	3	0
Breast mass	12	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	2	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	98	0
Breast swelling	13	0
Breast tenderness	11	0
Nipple pain	1	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	13	0
Erection increased	1	0
Nocturnal emission	1	0
Organic erectile dysfunction	10	0
Painful ejaculation	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	1	0
Lactation puerperal increased	2	0
Suppressed lactation	7	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	7	0
Premature menopause	3	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	10	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	331	0
Intermenstrual bleeding	168	0
Menstrual discomfort	2	0
Menstrual disorder	278	0
Menstruation irregular	447	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0
Premenstrual pain	15	0
Premenstrual syndrome	14	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Amenorrhoea	67	0
Hypomenorrhoea	87	0
Menstruation delayed	575	0
Oligomenorrhoea	22	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	761	0
Menometrorrhagia	7	0
Polymenorrhoea	112	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	7	0
Polycystic ovaries	7	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	16	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	12	0
Pelvic haemorrhage	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile pain	1	0
Penis disorder	3	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	2	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>		
Genital odour	1	0
Genital pain	1	0
Pelvic pain	17	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	9	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	3	0
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular mass	1	0
Testicular pain	15	0
Testicular swelling	4	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometriosis	12	0
Uterine haemorrhage	8	0
Uterine pain	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	12	0
<i>Vulvovaginal cysts and neoplasms</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	225	0
Vaginal ulceration	1	0
Vulval haemorrhage	7	0
<i>Vulvovaginal signs and symptoms</i>		
Labia enlarged	1	0
Vaginal discharge	12	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	3515	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	804	0
Dyspnoea at rest	1	0
Dyspnoea exertional	4	0
Hyperventilation	5	0
Hypopnoea	17	0
Hypoventilation	1	0
Irregular breathing	3	0
Respiration abnormal	14	0
Respiratory arrest	1	1
Respiratory distress	1	0
Sleep apnoea syndrome	2	0
Tachypnoea	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	46	0
Asthma exercise induced	1	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	1	0
Childhood asthma	1	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	76	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	2	0
Cough	388	0
Haemoptysis	2	0
Productive cough	24	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	3	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	14	0
Pulmonary haemorrhage	1	0
Pulmonary pain	19	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	47	0
Rhinitis allergic	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	131	0
Nasal dryness	2	0
Nasal oedema	2	0
Nasal pruritus	3	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Sinonasal obstruction	1	0
Sinus congestion	12	0
Sinus disorder	3	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal hypoaesthesia	2	0
Pharyngeal oedema	2	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	50	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	9	0
<i>Pleural infections and inflammations</i>		
Pleurisy	5	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	3	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	2	0
Pulmonary oedema	4	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	24	0
Pulmonary thrombosis	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	2	0
Respiratory symptom	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Respiratory disorder	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	11	0
Catarrh	2	0
Choking	4	0
Dry throat	19	0
Dysphonia	13	0
Increased viscosity of upper respiratory secretion	3	0
Nasal discomfort	7	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	377	0
Paranasal sinus discomfort	6	0
Rhinalgia	4	0
Rhinorrhoea	118	0
Sinus pain	48	0
Sneezing	38	0
Throat irritation	28	0
Throat tightness	42	0
Upper-airway cough syndrome	3	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Yawning	5	0
Respiratory disorders SOC TOTAL	2501	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	29	0
<i>Alopecias</i>		
Alopecia	40	0
Alopecia areata	7	0
Alopecia totalis	2	0
<i>Angioedemas</i>		
Angioedema	34	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	205	0
Hidradenitis	1	0
Hyperhidrosis	685	0
Miliaria	55	0
Night sweats	172	0
<i>Bullous conditions</i>		
Blister	51	0
Blister rupture	1	0
Blood blister	2	0
Dermatitis bullous	1	0
Erythema multiforme	11	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	74	0
Pain of skin	86	0
Papule	21	0
Scab	5	0
Scar pain	3	0
Sensitive skin	101	0
Skin burning sensation	46	0
Skin discolouration	29	0
Skin discomfort	1	0
Skin induration	8	0
Skin lesion	22	0
Skin necrosis	1	0
Skin odour abnormal	2	0
Skin reaction	97	0
Skin sensitisation	10	0
Skin swelling	16	0
Skin tightness	6	0
Skin warm	200	0
Yellow skin	3	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	26	0
Dermatitis allergic	86	0
Dermatitis atopic	11	0
Dermatitis contact	7	0
Dyshidrotic eczema	11	0
Eczema	48	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Eczema nummular	2	0
Neurodermatitis	1	0
Skin irritation	23	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	957	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	12	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Skin hypopigmentation	1	0
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychoclasia	1	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	3	0
<i>Papulosquamous conditions</i>		
Lichen planus	2	0
Pityriasis rosea	9	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	16	0
<i>Pilar disorders NEC</i>		
Piloerection	12	0
Trichodynia	1	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	1993	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	19	0
<i>Purpura and related conditions</i>		
Petechiae	17	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	2257	0
Rash erythematous	885	0
Rash macular	151	0
Rash maculo-papular	3	0
Rash morbilliform	5	0
Rash papular	151	0
Rash pruritic	490	0
Rash vesicular	5	0
<i>Rosaceas</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rosacea	2	0
Scaly conditions		
Pityriasis	2	0
Sebaceous gland disorders		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	0
Skin mass	8	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	3	0
Skin ulcer	4	0
Skin cysts and polyps		
Dermal cyst	7	0
Skin dystrophies		
Keloid scar	2	0
Skin wrinkling	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	2	0
Skin hypoplasias and atrophies		
Skin atrophy	2	0
Skin injuries and mechanical dermatoses		
Needle track marks	2	0
Skin vasculitides		
Cutaneous vasculitis	3	0
Vasculitic rash	1	0
Skin vasomotor conditions		
Livedo reticularis	4	0
Telangiectasia and related conditions		
Spider naevus	1	0
Urticarias		
Chronic spontaneous urticaria	1	0
Mechanical urticaria	1	0
Urticaria	381	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	2	0
Skin disorders SOC TOTAL	9699	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	1	0
Menopause	5	0
<i>Disability issues</i>		
Bedridden	4	0
Disability	1	0
Immobile	4	0
Impaired driving ability	2	0
Loss of personal independence in daily activities	1	0
Sight disability	2	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	5	0
<i>Social issues NEC</i>		
Social problem	1	0
Social circumstances SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	23	0
Immunisation	33	0
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	6	0
<i>Therapeutic procedures NEC</i>		
Bed rest	3	0
Botulinum toxin injection	1	0
Hospitalisation	4	0
Injection	26	0
Interchange of vaccine products	3	0
Localised alternating hot and cold therapy	1	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	116	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	2	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	5	0
Neurogenic shock	1	0
Shock	4	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	4	0
Haemorrhage	178	0
Internal haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	17	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Embolism venous	1	0
Thrombosis	32	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	6	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	4	0
Deep vein thrombosis	20	0
Pelvic venous thrombosis	1	0
Superficial vein thrombosis	1	0
Thrombophlebitis	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	8	0
Flushing	40	0
Hot flush	216	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Peripheral coldness	71	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	5	0
<i>Site specific vascular disorders NEC</i>		
Pallor	72	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	73	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	73	0
Orthostatic hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
Vascular disorders SOC TOTAL	872	0
TOTAL REACTIONS FOR DRUG	82698	23
TOTAL REPORTS	24721	
TOTAL FATAL OUTCOME REPORTS		23