

COVID-19 Moderna vaccine analysis print

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All UK spontaneous reports received between 9/12/2021 and 02/03/2022 for Moderna vaccine analysis print.

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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: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

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	9	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	6	0
Spontaneous haematoma	1	0
<i>Coagulopathies</i>		
Abnormal clotting factor	1	0
Antiphospholipid syndrome	2	0
Coagulopathy	3	0
Hypercoagulation	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	2	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	2	0
Mastocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	340	0
Lymph node ulcer	1	0
Lymphadenitis	25	0
Lymphadenopathy	2012	0
Lymphatic disorder	1	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	3	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	1	0
<i>Spleen disorders</i>		
Splenic infarction	1	0
Splenic vein thrombosis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	7	0
Thrombocytopenia	28	0
Thrombocytopenic purpura	2	0
Blood disorders SOC TOTAL	2457	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	3	0
Bundle branch block left	1	0
Bundle branch block right	2	0
Sinoatrial block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	15	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	4	0
Palpitations	1601	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
Toxic cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	1
Coronary artery disease	1	0
Coronary artery occlusion	1	0
Coronary artery stenosis	1	0
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	5	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	1	0
Acute myocardial infarction	2	0
Angina pectoris	60	0
Angina unstable	2	0
Myocardial infarction	31	1
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	7	0
Left ventricular dysfunction	3	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	1	0
Myocardial injury	1	0
Myocardial oedema	1	0
<i>Noninfectious myocarditis</i>		
Hypersensitivity myocarditis	1	0
Myocarditis	212	0
<i>Noninfectious pericarditis</i>		
Pericarditis	119	0
Pleuropericarditis	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	4	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Pericardial rub	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	29	0
Bradycardia	13	0
Cardiac fibrillation	1	0
Cardiac flutter	130	0
Extrasystoles	46	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	1	0
Tachyarrhythmia	3	0
Tachycardia	713	1
Tachycardia foetal	1	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	32	0
Atrial flutter	11	0
Atrial tachycardia	1	0
Sinus arrhythmia	1	0
Sinus tachycardia	10	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	6	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	15	4
Ventricular extrasystoles	4	0
Ventricular tachycardia	6	0
Cardiac disorders SOC TOTAL	3122	7

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	3	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 canal erythema	1	0
Ear congestion	7	0
Ear discomfort	8	0
Ear disorder	5	0
Ear inflammation	1	0
Ear pain	291	0
Ear swelling	6	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	50	0
Deafness transitory	1	0
Deafness unilateral	7	0
Hypoacusis	41	0
Sudden hearing loss	12	0
<i>Hyperacusia</i>		
Hyperacusis	9	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	3	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	19	0
Tinnitus	399	0
Vertigo	282	0
Vertigo labyrinthine	2	0
Vertigo positional	12	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1164	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	1	0
Thyroiditis subacute	2	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	7	0
Ovulation delayed	11	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	1	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Pituitary haemorrhage	1	0
<i>Polyglandular endocrine disorders</i>		
Polyglandular disorder	1	0
<i>Thyroid disorders NEC</i>		
Goitre	6	0
Thyroid disorder	1	0
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	4	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	4	0
Endocrine disorders SOC TOTAL	50	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	3	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	4	0
Vitreous detachment	2	0
Vitreous floaters	16	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	8	0
<i>Eyelid movement disorders</i>		
Blepharospasm	35	0
Eyelid ptosis	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	2	0
Iritis	2	0
Uveitis	11	0
<i>Lacrimation disorders</i>		
Dry eye	33	0
Lacrimation increased	15	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	2	0
Erythema of eyelid	2	0
Eyelid cyst	1	0
Eyelid irritation	1	0
Eyelid oedema	2	0
Eyelid rash	2	0
Swelling of eyelid	33	0
<i>Lid, lash and lacrimal structural disorders</i>		
Lagophthalmos	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
Eye haemorrhage	4	0
<i>Ocular disorders NEC</i>		
Eye disorder	3	0
Eye oedema	1	0
Eye pain	334	0
Eye swelling	129	0
Eyelid disorder	2	0
Eyelids pruritus	2	0
Ocular discomfort	12	0
Periorbital oedema	3	0
Periorbital swelling	19	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	3	0
Eye discharge	2	0
Eye inflammation	7	0
Eye irritation	18	0
Eye pruritus	38	0
Ocular hyperaemia	42	0
<i>Ocular nerve and muscle disorders</i>		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Extraocular muscle paresis	1	0
Eye movement disorder	7	0
Gaze palsy	1	0
Ocular sensation disorders		
Abnormal sensation in eye	2	0
Asthenopia	28	0
Foreign body sensation in eyes	7	0
Hypoaesthesia eye	6	0
Photophobia	131	0
Optic disc abnormalities NEC		
Optic discs blurred	1	0
Papilloedema	1	0
Optic nerve bleeding and vascular disorders		
Optic ischaemic neuropathy	1	0
Orbital infections, inflammations and irritations		
Orbital myositis	1	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	2	0
Pupil disorders		
Mydriasis	4	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Astigmatism	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	9	0
Retinal structural change, deposit and degeneration		
Retinal detachment	1	0
Retinopathies NEC		
Acute macular neuroretinopathy	1	0
Serous retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	5	0
Scleral structural change, deposit and degeneration		
Scleral disorder	1	0
Structural change, deposit and degeneration of eye NEC		
Exophthalmos	2	0
Visual colour distortions		
Cyanopsia	1	0
Xanthopsia	2	0
Visual disorders NEC		
Diplopia	29	0
Halo vision	4	0
Metamorphopsia	5	0
Photopsia	31	0
Scintillating scotoma	1	0
Vision blurred	293	0
Visual field disorders		
Visual field defect	5	0
Visual impairment and blindness (excl colour blindness)		
Blindness	32	0
Blindness transient	5	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Blindness unilateral	1	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	54	0
Eye disorders SOC TOTAL	1486	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	3	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	7	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	6	0
Colitis ischaemic	1	0
Colitis ulcerative	8	0
Crohn's disease	8	0
Inflammatory bowel disease	4	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 discomfort	1	0
Dental paraesthesia	5	0
Hyperaesthesia teeth	6	0
Toothache	35	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	1110	0
Diarrhoea haemorrhagic	5	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	148	0
Epigastric discomfort	3	0
Eructation	19	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	10	0
Faeces soft	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	74	0
Flatulence	39	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	2	0
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	10	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	328	0
Abdominal pain lower	24	0
Abdominal pain upper	844	0
Abdominal rigidity	3	0
Abdominal tenderness	5	0
Gastrointestinal pain	35	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	41	0
Gastric dilatation	2	0
Gastrooesophageal reflux disease	37	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	2	0
Functional gastrointestinal disorder	3	0
Gastric disorder	1	0
Gastrointestinal disorder	3	0
Lymphoid hyperplasia of intestine	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	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	165	0
Acute abdomen	1	0
Anal incontinence	3	0
Breath odour	8	0
Dysphagia	34	0
Odynophagia	8	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	8	0
Irritable bowel syndrome	17	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	2	0
Mesenteric vein thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	19	0
Gingival swelling	8	0
Noninfective gingivitis	2	0
<i>Gingival haemorrhages</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival bleeding	14	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	6	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	17	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	1	0
Nausea	4563	0
Regurgitation	1	0
Retching	30	0
Vomiting	1725	0
Vomiting projectile	19	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	3	0
Haematemesis	8	0
Haematochezia	14	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	104	0
Lip dry	9	0
Saliva altered	2	0
Salivary hypersecretion	12	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
Cheilitis	4	0
Enlarged uvula	1	0
Lip blister	3	0
Lip disorder	1	0
Oral 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	88	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	11	0
Lip pruritus	3	0
Oral discomfort	11	0
Oral mucosal blistering	2	0
Oral mucosal eruption	3	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	33	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral pruritus	2	0
Paraesthesia oral	124	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	1	0
Lip swelling	206	0
Mouth swelling	23	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	1	0
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 mass	1	0
Salivary gland pain	3	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	3	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	4	0
Lip ulceration	4	0
Mouth ulceration	95	0
Stomatitis	6	0
<i>Tongue disorders</i>		
Glossitis	7	0
Tongue disorder	9	0
Tongue haemorrhage	1	0
Tongue ulceration	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	30	0
Stiff tongue	1	0
Swollen tongue	91	0
Tongue blistering	3	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	5	0
Tongue dry	3	0
Tongue eruption	1	0
Tongue exfoliation	1	0
Tongue movement disturbance	1	0
Tongue oedema	3	0
Tongue pruritus	1	0
Tongue spasm	1	0
<i>Tooth missing</i>		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	10512	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	1	0
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	6	0
Puncture site pain	4	0
Vessel puncture site bruise	2	0
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site burn	1	0
Application site erythema	11	0
Application site inflammation	1	0
Application site joint erythema	1	0
Application site pain	3	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	4	0
<i>Asthenic conditions</i>		
Asthenia	572	0
Chronic fatigue syndrome	9	0
Decreased activity	1	0
Fatigue	6349	0
Malaise	1092	0
Sluggishness	2	0
<i>Body temperature altered</i>		
Hyperthermia	2	0
Hypothermia	5	0
Temperature regulation disorder	3	0
<i>Complications associated with device NEC</i>		
Injury associated with device	1	0
<i>Death and sudden death</i>		
Death	17	17
Sudden death	2	2
<i>Febrile disorders</i>		
Pyrexia	6692	1
<i>Feelings and sensations NEC</i>		
Chills	3995	0
Feeling abnormal	441	0
Feeling cold	387	0
Feeling drunk	17	0
Feeling hot	363	0
Feeling jittery	11	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Feeling of body temperature change	122	0
Hangover	21	0
Hunger	18	0
Sensation of blood flow	1	0
Sensation of foreign body	8	0
Temperature intolerance	22	0
Thirst	119	0
Thirst decreased	1	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	33	0
Gait inability	19	0
Loss of control of legs	4	0
General signs and symptoms NEC		
Condition aggravated	39	0
Crepitations	1	0
Crying	37	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	6	0
Foaming at mouth	2	0
General physical health deterioration	2	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	653	0
Induration	10	0
Influenza like illness	785	0
Irritability postvaccinal	1	0
Local reaction	27	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2176	0
Screaming	8	0
Secretion discharge	2	0
Swelling	1227	0
Swelling face	205	0
Implant and catheter site reactions		
Catheter site related reaction	1	0
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	197	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	2	0
Infusion site reactions		
Infusion site erythema	2	0
Infusion site mass	1	0
Infusion site pain	5	0
Infusion site pruritus	2	0
Infusion site urticaria	5	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	9	0
Injection site bruising	14	0
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	0
Injection site erythema	211	0
Injection site haemorrhage	3	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	16	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	2	0
Injection site mass	209	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	6	0
Injection site pain	854	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	135	0
Injection site rash	211	0
Injection site reaction	24	0
Injection site swelling	110	0
Injection site urticaria	58	0
Injection site vesicles	3	0
Injection site warmth	103	0
Interactions		
Alcohol interaction	2	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	8	0
Mass	29	0
Nodule	6	0
Mucosal findings abnormal		
Enanthema	1	0
Mucosal discolouration	1	0
Mucosal pain	1	0
Oedema mucosal	1	0
Polyp	1	0
Necrosis NEC		
Necrosis	1	0
Oedema NEC		
Face oedema	8	0
Localised oedema	6	0
Oedema	18	0
Oedema peripheral	14	0
Pain and discomfort NEC		
Axillary pain	902	0
Chest discomfort	448	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Chest pain	1719	0
Discomfort	128	0
Facial discomfort	1	0
Facial pain	41	0
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	2	0
Pain	2654	0
Tenderness	203	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	63	0
Adverse reaction	6	0
Drug ineffective	17	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
Therapeutic product effect decreased	1	0
Therapeutic response changed	1	0
Therapeutic response unexpected	2	0
Treatment failure	1	0
Vaccination failure	6	0
Ulcers NEC		
Ulcer	5	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	15	0
Vaccination site bruising	27	0
Vaccination site discolouration	2	0
Vaccination site discomfort	9	0
Vaccination site eczema	1	0
Vaccination site erythema	301	0
Vaccination site haemorrhage	6	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	21	0
Vaccination site inflammation	16	0
Vaccination site irritation	3	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	2	0
Vaccination site joint pain	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	2	0
Vaccination site macule	1	0
Vaccination site mass	83	0
Vaccination site movement impairment	20	0
Vaccination site oedema	1	0
Vaccination site pain	384	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	71	0
Vaccination site rash	149	0
Vaccination site reaction	8	0
Vaccination site scar	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site swelling	204	0
Vaccination site urticaria	13	0
Vaccination site vesicles	3	0
Vaccination site warmth	139	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	1	0
Withdrawal syndrome	7	0
General disorders SOC TOTAL	35627	21

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
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 failure and associated disorders</i>		
Acute hepatic failure	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	13	0
Liver tenderness	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
Hepatic steatosis	1	0
Hepatitis	2	0
Immune-mediated hepatitis	1	0
Liver injury	2	0
Hepatic disorders SOC TOTAL	41	0

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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	352	0
Infusion related hypersensitivity reaction	13	0
Multiple allergies	4	0
Serum sickness	3	0
Serum sickness-like reaction	1	0
Type I hypersensitivity	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	13	0
Food allergy	3	0
Milk allergy	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	70	0
Anaphylactic shock	7	0
Anaphylactoid reaction	10	0
<i>Atopic disorders</i>		
Seasonal allergy	16	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	52	0
Immune system disorder	4	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	598	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	10	0
Appendicitis perforated	1	0
Diverticulitis	5	0
Dysentery	1	0
Gastroenteritis	6	0
Peritonitis	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Bacterial infection	3	0
Cellulitis	77	0
Folliculitis	1	0
Injection site cellulitis	2	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
<i>Borrelial infections</i>		
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	10	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	8	0
Oral candidiasis	6	0
Vulvovaginal candidiasis	9	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Central nervous system infection	1	0
Meningitis	4	0
Meningitis aseptic	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	1	0
COVID-19	323	0
COVID-19 pneumonia	6	0
Coronavirus infection	1	0
Post-acute COVID-19 syndrome	2	0
Suspected COVID-19	3	0
<i>Coxiella infections</i>		
Q fever	7	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus infection reactivation	2	0
Pneumonia cytomegaloviral	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	2	0
Sialoadenitis	1	0
Tooth abscess	1	0
Tooth infection	2	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Ear infections</i>		
Ear infection	10	0
Labyrinthitis	13	0
Otitis externa	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
Lice infestation	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	2	0
<i>Eye and eyelid infections</i>		
Chorioretinitis	1	0
Conjunctivitis	13	0
Eye infection	3	0
Eyelid boil	1	0
Hordeolum	4	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	3	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
<i>Fusobacterium infections</i>		
Necrotising ulcerative gingivostomatitis	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	2	0
Genital herpes	14	0
Herpes ophthalmic	1	0
Herpes simplex	7	0
Herpes simplex reactivation	1	0
Herpes zoster	117	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	92	0
Varicella	3	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	1	0
Abscess limb	2	0
Abscess rupture	1	0
Empyema	1	1
Infection	89	0
Injection site infection	1	0
Localised infection	19	0
Lymph gland infection	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Lymph node abscess	3	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	5	0
Vaccine breakthrough infection	1	0
Vestibulitis	1	0
Wound infection	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	583	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
Bronchitis	6	0
Lower respiratory tract infection	65	1
Pleural infection	1	0
Pneumonia	14	1
Pneumonia aspiration	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	1	0
Orchitis	3	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Nematode infections</i>		
Enterobiasis	1	0
<i>Orthopox viral infections</i>		
Vaccinia virus infection	1	0
<i>Parvoviral infections</i>		
Erythema infectiosum	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	5	0
Septic shock	1	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Blister infected	1	0
Eczema infected	1	0
Impetigo	6	0
Infected skin ulcer	1	0
Pustule	11	0
Pyoderma	1	0
Rash pustular	3	0
Skin infection	14	0
Vaccination site pustule	1	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Staphylococcal infections</i>		
Furuncle	10	0
<i>Streptococcal infections</i>		
Pharyngitis streptococcal	1	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea infection	1	0
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	2	0
Chronic sinusitis	1	0
Laryngitis	6	0
Nasopharyngitis	302	0
Peritonsillar abscess	1	0
Pharyngitis	6	0
Rhinitis	8	0
Sinusitis	32	0
Tonsillitis	15	0
Upper respiratory tract infection	3	0
<i>Urinary tract infections</i>		
Cystitis	11	0
Kidney infection	4	0
Urinary tract infection	39	0
<i>Vascular infections</i>		
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	1	0
Gastroenteritis viral	3	0
Meningitis viral	2	0
Post viral fatigue syndrome	8	0
Sweating fever	57	0
Vestibular neuronitis	4	0
Viral infection	7	0
Viral labyrinthitis	2	0
Viral pharyngitis	6	0
Viral rash	7	0
Infections SOC TOTAL	2234	4

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Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Palate injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	2	0
<i>Cardiovascular injuries</i>		
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Concussion	8	0
Subdural haematoma	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	3	0
<i>Conditions caused by cold</i>		
Chillblains	15	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	25	0
Foetal exposure during pregnancy	11	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	557	0
Maternal exposure during pregnancy	264	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>		
Blindness traumatic	1	0
Eye contusion	2	0
Eye injury	5	0
<i>Fractures and dislocations NEC</i>		
Compression fracture	1	0
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Procedural vomiting	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	8	0
Heat stroke	8	0
<i>Limb fractures and dislocations</i>		
Clavicle fracture	8	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	16	0
Wrong schedule	1	0
Wrong technique in device usage process	1	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Epicondylitis	3	0
Ligament sprain	2	0
Muscle injury	5	0
Muscle strain	5	0
Tendon injury	2	0
Tendon rupture	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	21	0
Nerve root injury lumbar	1	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	5	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Arthropod bite	4	0
Bite	1	0
Electric shock	6	0
Fall	33	0
Inflammation of wound	2	0
Injury	4	0
Multiple injuries	1	0
Nervous system injury	1	0
Stab wound	1	0
Struck by lightning	1	0
Wound complication	7	0
Wound haemorrhage	2	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Infusion related reaction	1	0
Injection related reaction	24	0
Post procedural complication	1	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	22	0
<i>Overdoses NEC</i>		
Overdose	6	0
<i>Peripheral nerve injuries</i>		
Sciatic nerve injury	1	0
Ulnar 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	65	0
Expired product administered	31	0
Extra dose administered	3	0
Inappropriate schedule of product administration	54	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	9	0
Incorrect product administration duration	1	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Incorrect route of product administration	2	0
Poor quality product administered	1	0
Product administered at inappropriate site	4	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	2	0
Product dispensing errors and issues		
Product dispensing error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	1	0
Radiation injuries		
Sunburn	15	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Site specific injuries NEC		
Back injury	2	0
Head injury	10	0
Limb injury	44	0
Skin injuries NEC		
Contusion	333	0
Scar	11	0
Scratch	2	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	1	0
Subcutaneous haematoma	2	0
Skull fractures, facial bone fractures and dislocations		
Jaw fracture	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Stoma complications		
Stoma site discomfort	1	0
Stoma site oedema	1	0
Thermal burns		
Burn oesophageal	1	0
Cold burn	1	0
Thermal burn	13	0
Thermal burns of eye	6	0
Thoracic cage fractures and dislocations		
Sternal fracture	1	0
Vaccination related complications		
Vaccination complication	15	0
Injuries SOC TOTAL	1772	0

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal medulla tests</i>		
Norepinephrine increased	2	0
<i>Auditory and vestibular diagnostic procedures</i>		
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Rheumatoid factor increased	1	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>		
Blood lactic acid	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	2	0
Oxygen saturation decreased	15	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	1	0
Blood glucose decreased	2	0
Blood glucose increased	7	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	4	0
Heart sounds	5	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>Chemistry analyses NEC</i>		
Histamine abnormal	1	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	1	0
Low density lipoprotein increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time	1	0
Bleeding time abnormal	1	0
Blood fibrinogen	1	0
Blood thrombin	1	0
Coagulation time shortened	1	0
Fibrin D dimer increased	5	0
International normalised ratio decreased	1	0
International normalised ratio increased	1	0
<i>Digestive enzymes</i>		
Amylase 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	3	0
Electrocardiogram change	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	15	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<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>Gastrointestinal function diagnostic procedures</i>		
Gastric pH decreased	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	258	0
Heart rate abnormal	22	0
Heart rate decreased	14	0
Heart rate increased	391	0
Heart rate irregular	75	0
Heart rate variability decreased	1	0
Maximum heart rate	1	0
Maximum heart rate increased	1	0
Pulse abnormal	1	0
Pulse absent	1	0
Sinus rhythm	3	0
<i>Imaging procedures NEC</i>		
X-ray	1	0
<i>Immunology analyses NEC</i>		
Immunology test	1	0
<i>Investigations NEC</i>		
Blood test	1	0
Blood test abnormal	5	0
Blood test normal	1	0
Polymerase chain reaction positive	2	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase	2	0
Bile output	3	0
Blood bilirubin increased	1	0
Liver function test abnormal	7	0
Liver function test increased	1	0
Transaminases increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood calcium increased	2	0
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Urine copper	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone scan	1	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Tender joint count	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Sensory level	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Visual tracking test	1	0
Visual tracking test abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	98	0
Body temperature abnormal	11	0
Body temperature decreased	16	0
Body temperature fluctuation	24	0
Body temperature increased	112	0
Breath sounds	1	0
Breath sounds abnormal	1	0
Grip strength	1	0
Grip strength decreased	2	0
Head lag	4	0
Lymph node palpable	5	0
Muscle strength abnormal	2	0
Ophthalmological examination	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	4	0
Respiratory rate decreased	6	0
Respiratory rate increased	10	0
Skin temperature	23	0
Temperature difference of extremities	5	0
Weight decreased	21	0
Weight increased	10	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	10	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	8	0
<i>Red blood cell analyses</i>		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
<i>Reproductive hormone analyses</i>		
Blood testosterone decreased	1	0
False negative pregnancy test	1	0
Pregnancy test	1	0
Pregnancy test false positive	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Smear cervix	1	0
<i>Reproductive organ and breast imaging procedures</i>		
Hysteroscopy	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume decreased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Forced expiratory volume increased	2	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	1	0
Myocardial necrosis marker increased	1	0
Troponin I increased	1	0
Troponin T increased	1	0
Troponin increased	5	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	5	0
<i>Thyroid analyses</i>		
Tri-iodothyronine decreased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
Blood lactate dehydrogenase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine	5	0
Blood urine present	25	0
Protein urine	1	0
pH urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	12	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	2	0
Blood pressure decreased	11	0
Blood pressure diastolic increased	1	0
Blood pressure increased	32	0
Blood pressure measurement	7	0
Blood pressure normal	1	0
<i>Virus identification and serology</i>		
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	7	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count	1	0
Neutrophil count decreased	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	1454	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	414	0
Food craving	2	0
Food refusal	4	0
Hyperphagia	5	0
Hypophagia	2	0
Increased appetite	9	0
Salt craving	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	5	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	19	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	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	2	0
Food intolerance	2	0
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	3	0
Abnormal weight gain	8	0
Feeding disorder	46	0
Food aversion	5	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	7	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	9	0
<i>Iron excess</i>		
Haemochromatosis	1	0
<i>Potassium imbalance</i>		
Hypokalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	102	0
<i>Total fluid volume increased</i>		
Fluid retention	10	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	1	0
Metabolic disorders SOC TOTAL	682	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	52	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	9	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	1	0
<i>Bone disorders NEC</i>		
Bone erosion	1	0
Exostosis	2	0
Jaw cyst	1	0
Jaw disorder	1	0
Medial tibial stress syndrome	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	105	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	97	0
Spinal pain	16	0
<i>Bursal disorders</i>		
Bursitis	24	0
<i>Cartilage disorders</i>		
Costochondritis	20	0
<i>Connective tissue disorders NEC</i>		
Morphoea	1	0
Polymyalgia rheumatica	4	0
Reynold's syndrome	2	0
<i>Extremity deformities</i>		
Finger deformity	1	0
Foot deformity	2	0
Hand deformity	2	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	2	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	1	0
Joint lock	10	0
Periarthritis	50	0
Rotator cuff syndrome	5	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2469	0
Joint effusion	1	0
Joint noise	3	0
Joint range of motion decreased	1	0
Joint stiffness	69	0
Joint swelling	82	0
Joint vibration	2	0
Joint warmth	7	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Muscle infections and inflammations</i>		
Myositis	9	0
<i>Muscle pains</i>		
Fibromyalgia	24	0
Myalgia	3230	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	2	0
Muscle discomfort	2	0
Muscle fatigue	104	0
Muscle haemorrhage	1	0
Muscle spasms	482	0
Muscle swelling	16	0
Muscle tightness	29	0
Muscle twitching	91	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	4	0
Nuchal rigidity	5	0
Trismus	9	0
<i>Muscle weakness conditions</i>		
Muscular weakness	225	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Limb mass	2	0
Mastication disorder	2	0
Mobility decreased	20	0
Muscle contracture	1	0
Musculoskeletal disorder	2	0
Musculoskeletal stiffness	459	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	2	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	797	0
Flank pain	18	0
Limb discomfort	382	0
Musculoskeletal chest pain	62	0
Musculoskeletal discomfort	22	0
Musculoskeletal pain	24	0
Neck pain	471	0
Pain in extremity	3843	1
Sacral pain	1	0
<i>Myopathies</i>		
Rhabdomyolysis	1	0
<i>Osteoarthropathies</i>		
Osteoarthritis	5	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	3	0
<i>Rheumatoid arthropathies</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Rheumatoid arthritis	16	0
Soft tissue disorders NEC		
Axillary mass	58	0
Fluctuance	1	0
Groin pain	26	0
Neck mass	13	0
Soft tissue swelling	2	0
Spondyloarthropathies		
Ankylosing spondylitis	4	0
Arthritis reactive	16	0
Axial spondyloarthritis	1	0
Synovial disorders		
Synovial cyst	5	0
Tendon disorders		
Tendon pain	4	0
Tendonitis	6	0
Trigger finger	3	0
Trunk deformities		
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	13568	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma stage II	1	0
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	4	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Leukaemias NEC</i>		
Leukaemia	2	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	9	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>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal carcinoma	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>		
Acrochordon	1	0
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	4	0
<i>Small intestinal neoplasms malignant</i>		
Small intestine adenocarcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Urinary tract neoplasms unspecified malignancy NEC</i>		
Renal neoplasm	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	2	0
Neoplasms SOC TOTAL	42	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	5	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	16	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
Orthostatic intolerance	3	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	0
Cerebral haemorrhage	4	2
Cerebral infarction	1	0
Cerebrovascular accident	32	1
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	3	0
Ruptured cerebral aneurysm	1	1
Subarachnoid haemorrhage	5	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	4	0
Cerebral venous thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical radiculopathy	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	1	0
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	3	0
Balance disorder	86	0
Coordination abnormal	7	0
Dysstasia	14	0
Nystagmus	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	6	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	13	0
Lethargy	493	0
Loss of consciousness	262	0
Somnolence	263	0
Stupor	1	0
Syncope	1083	0
<i>Disturbances in sleep phase rhythm</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Delayed sleep phase	1	0
Dyskinesias and movement disorders NEC		
Akathisia	1	0
Bradykinesia	4	0
Clumsiness	4	0
Dyskinesia	13	0
Extrapyramidal disorder	2	0
Fine motor delay	1	0
Fine motor skill dysfunction	4	0
Foetal movement disorder	1	0
Hyperkinesia	1	0
Hypokinesia	19	0
Motor dysfunction	3	0
Movement disorder	13	0
Psychomotor hyperactivity	4	0
Dystonias		
Dystonia	1	0
Encephalitis NEC		
Noninfective encephalitis	1	0
Eye movement disorders		
IVth nerve paresis	1	0
Facial cranial nerve disorders		
Bell's palsy	101	0
Facial nerve disorder	1	0
Facial paralysis	56	0
Facial paresis	12	0
Facial spasm	7	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	8	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cluster headache	64	0
Cold-stimulus headache	11	0
Drug withdrawal headache	2	0
Headache	8007	0
Medication overuse headache	1	0
New daily persistent headache	2	0
Occipital neuralgia	1	0
Primary cough headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	103	0
Tension headache	168	0
Thunderclap headache	3	0
Vascular headache	7	0
Hydrocephalic conditions		
Hydrocephalus	1	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	3	0
Lumbar spinal cord and nerve root disorders		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Sciatica	12	0
Memory loss (excl dementia)		
Amnesia	50	0
Memory impairment	34	0
Transient global amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	18	0
Disturbance in attention	82	0
Mental impairment	14	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	6	0
Migraine	819	0
Migraine with aura	46	0
Migraine without aura	3	0
Retinal migraine	4	0
Typical aura without headache	1	0
Vestibular migraine	4	0
Mononeuropathies		
Carpal tunnel syndrome	5	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	4	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	3	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	5	0
Muscle tone abnormal		
Drop attacks	1	0
Hypotonia	10	0
Stiff leg syndrome	3	0
Myelitis (incl infective)		
Myelitis transverse	2	0
Narcolepsy and hypersomnia		
Hypersomnia	29	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	5	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Tunnel vision	13	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Clonus	1	0
Dizziness	3184	0
Dizziness exertional	11	0
Dizziness postural	210	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	65	0
Meningism	1	0
Neurological symptom	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Persistent postural-perceptual dizziness	2	0
Presyncope	249	0
Tongue biting	2	0
Unresponsive to stimuli	12	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	39	0
Hyposmia	2	0
Parosmia	43	0
Optic nerve disorders NEC		
Optic neuritis	5	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	5	0
Burning sensation	120	0
Dysaesthesia	1	0
Formication	7	0
Hemianaesthesia	2	0
Hyperaesthesia	54	0
Hypoaesthesia	652	0
Paraesthesia	941	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	3	0
Hemiparesis	4	0
Hemiplegia	8	0
Monoparesis	24	0
Monoplegia	27	0
Paralysis	32	0
Paraparesis	1	0
Paresis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	12	0
Reduced facial expression	1	0
Peripheral neuropathies NEC		
Autoimmune neuropathy	2	0
Neuralgic amyotrophy	3	0
Neuritis	2	0
Neuropathy peripheral	13	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
Seizures and seizure disorders NEC		
Epilepsy	23	0
Febrile convulsion	5	0
Myoclonic epilepsy	1	0
Partial seizures	7	0
Psychogenic seizure	1	0
Seizure	181	0
Seizure anoxic	1	0
Seizure cluster	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Status epilepticus	28	0
Tonic clonic movements	3	0
Tonic convulsion	5	0
Sensory abnormalities NEC		
Ageusia	86	0
Allodynia	3	0
Aura	3	0
Complex regional pain syndrome	1	0
Dysgeusia	225	0
Electric shock sensation	13	0
Hypogeusia	1	0
Neuralgia	137	0
Post herpetic neuralgia	3	0
Restless legs syndrome	44	0
Sensory disturbance	20	0
Sensory loss	33	0
Taste disorder	50	0
Vibratory sense increased	2	0
Sleep disturbances NEC		
Sleep deficit	5	0
Speech and language abnormalities		
Dysarthria	33	0
Incoherent	10	0
Slow speech	5	0
Speech disorder	15	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	3	0
Radiculopathy	1	0
Transient cerebrovascular events		
Transient ischaemic attack	20	0
Tremor (excl congenital)		
Essential tremor	1	0
Head titubation	2	0
Tremor	651	0
Trigeminal disorders		
Trigeminal neuralgia	6	0
Nervous system disorders SOC TOTAL	19540	4

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	63	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>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	4	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>Multiple pregnancies</i>		
Twin 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
<i>Stillbirth and foetal death</i>		
Stillbirth	1	1
<i>Umbilical cord complications</i>		
Umbilical cord thrombosis	1	0
Pregnancy conditions SOC TOTAL	94	1

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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>		
Oversensing	1	0
Thrombosis in device	2	0
Undersensing	2	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	25	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	6	0
Breath holding	3	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	3	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	22	0
Anxiety	250	0
Nervousness	48	0
Stress	21	0
Tension	10	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	4	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Disinhibition	1	0
Homicidal ideation	1	0
Impatience	1	0
Paranoia	6	0
Personality change	2	0
Social avoidant behaviour	1	0
Violence-related symptom	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
Mental fatigue	58	0
<i>Communications disorders</i>		
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	208	0
Disorientation	86	0
<i>Deliria</i>		
Delirium	49	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	91	0
Depression suicidal	4	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Dissociation	13	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	7	0
Insomnia	477	0
Middle insomnia	14	0
Terminal insomnia	13	0
<i>Dyssomnias</i>		
Poor quality sleep	92	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	14	0
Emotional disorder	21	0
Emotional distress	11	0
Emotional poverty	1	0
Euphoric mood	12	0
Frustration tolerance decreased	4	0
Irritability	52	0
Mood altered	18	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	5	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
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	18	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	120	0
Hallucination, auditory	6	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	4	0
Hallucinations, mixed	2	0
Somatic hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	60	0
<i>Mental disorders NEC</i>		
Mental disorder	4	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	1	0
Depressed mood	94	0
Feeling of despair	5	0
Negative thoughts	1	0
Sense of a foreshortened future	1	0
Tearfulness	7	0
<i>Mood alterations with manic symptoms</i>		
Mania	4	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Mood disorders NEC</i>		
Affective disorder	1	0
Apathy	12	0
Listless	7	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Dermatophagia	2	0
<i>Orgasmic disorders and disturbances</i>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	56	0
Panic reaction	12	0
<i>Paraphilias and paraphilic disorders</i>		
Exhibitionism	1	0
<i>Parasomnias</i>		
Abnormal dreams	38	0
Abnormal sleep-related event	1	0
Nightmare	59	0
Sleep inertia	1	0
Sleep talking	2	0
Sleep terror	5	0
Somnambulism	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Deja vu	1	0
Derealisation	3	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	13	0
<i>Psychiatric symptoms NEC</i>		
Helplessness	1	0
Hypervigilance	2	0
Psychiatric symptom	4	0
Psychological trauma	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic disorder	2	0
<i>Sexual desire disorders</i>		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	5	0
<i>Sleep disorders NEC</i>		
Sleep disorder	75	0
<i>Somatic symptom disorders</i>		
Conversion disorder	4	0
Habit cough	7	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	4	0
Head banging	6	0
<i>Stress disorders</i>		
Acute stress disorder	1	0
Post-traumatic stress disorder	1	0
<i>Substance related and addictive disorders</i>		
Alcoholism	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Suicidal behaviour	2	0
Suicidal ideation	19	0
Suicide attempt	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	4	0
Intrusive thoughts	1	0
Tachyphrenia	3	0
Thinking abnormal	4	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	2388	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder irritation	1	0
Bladder pain	10	0
Dysuria	9	0
Incontinence	11	0
Micturition urgency	11	0
Pollakiuria	41	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	13	0
Urinary retention	6	0
Urinary straining	1	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	2	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>		
Glomerulonephritis acute	1	0
IgA nephropathy	2	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
Hypertonic bladder	2	0
Loss of bladder sensation	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	6	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	2	0
Renal impairment	2	0
<i>Urinary abnormalities</i>		
Chromaturia	20	0
Haematuria	9	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	8	0
Nocturia	1	0
Renal pain	104	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	287	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	6	0
<i>Breast disorders NEC</i>		
Breast enlargement	4	0
Breast mass	18	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	4	0
<i>Breast signs and symptoms</i>		
Breast discharge	3	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	145	0
Breast swelling	22	0
Breast tenderness	13	0
Nipple pain	2	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation failure	2	0
Erectile dysfunction	14	0
Erection increased	1	0
Nocturnal emission	1	0
Organic erectile dysfunction	9	0
Painful ejaculation	1	0
Priapism	1	0
Spontaneous penile erection	1	0
<i>Gender disorders</i>		
Feminisation acquired	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	10	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	10	0
Premature menopause	4	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	20	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	471	0
Intermenstrual bleeding	252	0
Menstrual discomfort	4	0
Menstrual disorder	403	0
Menstruation irregular	673	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Premenstrual pain	23	0
Premenstrual syndrome	17	0
Withdrawal bleed	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	95	0
Hypomenorrhoea	115	0
Menstruation delayed	820	0
Oligomenorrhoea	32	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1055	0
Menometrorrhagia	9	0
Polymenorrhoea	174	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	7	0
Polycystic ovaries	10	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovulation pain	21	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	20	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 blister	1	0
Genital haemorrhage	3	0
Genital paraesthesia	1	0
Genital ulceration	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital odour	1	0
Genital pain	2	0
Pelvic discomfort	1	0
Pelvic pain	32	0
<i>Scrotal disorders NEC</i>		
Scrotal pain	8	0
Scrotal swelling	1	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	4	0
Sexual dysfunction	2	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0
Testicular mass	1	0
Testicular pain	21	0
Testicular swelling	5	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	21	0
Metrorrhoea	1	0
Uterine haemorrhage	12	0
Uterine pain	8	0
<i>Uterine neoplasms</i>		
Uterine polyp	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	15	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	334	0
Vaginal ulceration	3	0
Vulval haemorrhage	10	0
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	19	0
Vaginal odour	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	6	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	5063	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	1542	0
Dyspnoea at rest	1	0
Dyspnoea exertional	6	0
Hyperventilation	15	0
Hypopnoea	30	0
Hypoventilation	1	0
Irregular breathing	6	0
Mouth breathing	1	0
Respiration abnormal	23	0
Respiratory arrest	1	1
Respiratory distress	2	0
Sleep apnoea syndrome	4	0
Tachypnoea	7	0
<i>Bronchospasm and obstruction</i>		
Asthma	76	0
Asthma exercise induced	2	0
Asthma late onset	1	0
Asthmatic crisis	1	0
Bronchospasm	2	0
Childhood asthma	2	0
Chronic obstructive pulmonary disease	1	0
Obstructive airways disorder	1	0
Wheezing	119	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	3	0
Cough	599	0
Haemoptysis	4	0
Productive cough	37	0
Sputum discoloured	5	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	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonitis	5	0
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	16	0
Lower respiratory tract congestion	1	0
Pleuritic pain	2	0
Pulmonary haemorrhage	1	0
Pulmonary pain	27	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	65	0
Nasal inflammation	1	0
Rhinitis allergic	1	0
<i>Nasal disorders NEC</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Epistaxis	191	0
Nasal dryness	3	0
Nasal oedema	2	0
Nasal pruritus	3	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	5	0
Sinus congestion	13	0
Sinus disorder	4	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	2	0
Pharyngeal hypoaesthesia	4	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	62	0
Tonsillar erythema	3	0
Tonsillar hypertrophy	14	0
Tonsillar inflammation	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	9	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	4	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	5	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	64	1
Pulmonary thrombosis	3	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	4	0
Painful respiration	4	0
Respiratory symptom	3	0
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Pulmonary mass	1	0
Respiratory disorder	2	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	18	0
Catarrh	6	0
Choking	6	0
Dry throat	29	0
Dysphonia	24	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	8	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	3	0
Oropharyngeal pain	566	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	170	0
Sinus pain	75	0
Sneezing	57	0
Throat irritation	43	0
Throat tightness	53	0
Upper-airway cough syndrome	5	0
Yawning	9	0
Respiratory disorders SOC TOTAL	4136	2

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	37	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<i>Alopecias</i>		
Alopecia	59	0
Alopecia areata	14	0
Alopecia totalis	2	0
<i>Angioedemas</i>		
Angioedema	57	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	278	0
Hidradenitis	1	0
Hyperhidrosis	956	0
Miliaria	70	0
Night sweats	307	0
<i>Bullous conditions</i>		
Blister	92	0
Blister rupture	2	0
Blood blister	3	0
Dermatitis bullous	2	0
Erythema multiforme	15	0
Pemphigoid	1	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	102	0
Pain of skin	139	0
Papule	21	0
Scab	5	0
Scar pain	6	0
Sensitive skin	143	0
Skin burning sensation	74	0
Skin discolouration	40	0
Skin discomfort	2	0
Skin disorder	2	0
Skin induration	8	0
Skin lesion	26	0
Skin necrosis	2	0
Skin odour abnormal	3	0
Skin plaque	1	0
Skin reaction	122	0
Skin sensitisation	15	0
Skin swelling	28	0
Skin tightness	7	0
Skin warm	235	0
Skin weeping	2	0
Yellow skin	4	0
<i>Dermatitis and eczema</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Autoimmune dermatitis	1	0
Dermatitis	46	0
Dermatitis allergic	113	0
Dermatitis atopic	17	0
Dermatitis contact	8	0
Dyshidrotic eczema	12	0
Eczema	81	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Flagellate dermatitis	1	0
Hand dermatitis	1	0
Neurodermatitis	1	0
Skin irritation	35	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	4	0
Fixed eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	1187	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative generalised	1	1
Exfoliative rash	2	0
Skin exfoliation	19	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>		
Nail discolouration	1	0
Nail ridging	1	0
Onychalgia	1	0
Onychoclasia	1	0
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	10	0
<i>Papulosquamous conditions</i>		
Lichen planus	4	0
Parapsoriasis	1	0
Pityriasis rosea	17	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	19	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	16	0
Trichodynia	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Pruritus NEC</i>		
Itching scar	4	0
Pruritus	2498	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	2	0
Palmoplantar pustulosis	1	0
Psoriasis	29	0
Rebound psoriasis	1	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	23	0
Purpura	12	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	2862	0
Rash erythematous	1086	0
Rash macular	194	0
Rash maculo-papular	5	0
Rash morbilliform	8	0
Rash papular	184	0
Rash pruritic	606	0
Rash vesicular	11	0
<i>Rosaceas</i>		
Rosacea	2	0
<i>Scaly conditions</i>		
Pityriasis	4	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	2	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	4	0
Skin mass	11	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin erosion	6	0
Skin ulcer	6	0
<i>Skin cysts and polyps</i>		
Dermal cyst	8	0
<i>Skin dystrophies</i>		
Keloid scar	2	0
Skin wrinkling	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	3	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	3	0
<i>Skin injuries and mechanical dermatoses</i>		
Needle track marks	2	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	3	0
Vasculitic rash	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	5	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0

Case Series Drug Analysis Print

Name: COVID-19 Moderna vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Skin disorders		
Skin disorders cont'd		
<i>Urticarias</i>		
Chronic spontaneous urticaria	3	0
Cold urticaria	1	0
Idiopathic urticaria	4	0
Mechanical urticaria	21	0
Urticaria	673	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	7	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticarial vasculitis	1	0
Skin disorders SOC TOTAL	12817	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Menarche	2	0
Menopause	8	0
Postmenopause	2	0
<i>Disability issues</i>		
Bedridden	8	0
Disability	1	0
Immobile	4	0
Impaired driving ability	2	0
Impaired work ability	1	0
Loss of personal independence in daily activities	2	0
Sight disability	2	0
<i>Employment issues</i>		
Retirement	2	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	6	0
<i>Social issues NEC</i>		
Social problem	1	0
Tattoo	1	0
Social circumstances SOC TOTAL	44	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	2	0
<i>Contraceptive methods female</i>		
Post coital contraception	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
<i>Eye therapeutic procedures NEC</i>		
Eye irrigation	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	2	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	3	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	19	0
Immunisation	21	0
<i>Joint therapeutic procedures</i>		
Joint injection	1	0
Joint stabilisation	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	3	0
<i>Therapeutic procedures NEC</i>		
Bed rest	4	0
Botulinum toxin injection	1	0
Hospitalisation	3	0
Injection	17	0
Interchange of vaccine products	21	0
Polypectomy	1	0
Surgical & medical procedures SOC TOTAL	108	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

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	3	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	3	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	8	0
Neurogenic shock	1	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Bloody discharge	2	0
Haematoma	7	0
Haemorrhage	231	0
Internal haemorrhage	3	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	29	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	3	0
Embolism venous	1	0
Thrombosis	61	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	8	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	2	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	5	0
Deep vein thrombosis	51	0
Pelvic venous thrombosis	2	0
Superficial vein thrombosis	2	0
Thrombophlebitis	5	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	11	0
Erythromelalgia	1	0
Flushing	57	0
Hot flush	307	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Peripheral coldness	106	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	8	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Site specific vascular disorders NEC</i>		
Pallor	86	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	5	0
Varicose vein ruptured	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	106	0
Prehypertension	1	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Hypotension	101	0
Orthostatic hypotension	6	0
<i>Vasculitides NEC</i>		
Vasculitis	6	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1257	0
TOTAL REACTIONS FOR DRUG	120577	41
TOTAL REPORTS	36226	
TOTAL FATAL OUTCOME REPORTS		41