

## COVID-19 Moderna Vaccine Analysis Print

All UK spontaneous reports received up to and including 15/06/2022 for COVID-19 vaccine Moderna.

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: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Iron deficiency anaemia	2	0
<i><b>Anaemias NEC</b></i>		
Anaemia	18	0
Autoimmune anaemia	1	0
Microcytic anaemia	1	0
<i><b>Anaemias haemolytic NEC</b></i>		
Haemolytic anaemia	2	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	7	0
Spontaneous haematoma	1	0
<i><b>Coagulopathies</b></i>		
Abnormal clotting factor	2	0
Antiphospholipid syndrome	3	0
Coagulopathy	3	0
Hypercoagulation	2	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	2	0
<i><b>Haematological disorders</b></i>		
Blood disorder	1	0
Mast cell activation syndrome	3	0
Mastocytosis	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymph node pain	350	0
Lymph node ulcer	1	0
Lymphadenitis	27	0
Lymphadenopathy	2075	0
Lymphatic disorder	1	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Aplastic anaemia	1	0
<i><b>Neutropenias</b></i>		
Autoimmune neutropenia	1	0
Neutropenia	3	0
<i><b>Platelet disorders NEC</b></i>		
Platelet disorder	1	0
<i><b>Polycythaemia (excl rubra vera)</b></i>		
Stress polycythaemia	1	0
<i><b>Sickle cell trait and disorders</b></i>		
Sickle cell anaemia with crisis	1	0
<i><b>Spleen disorders</b></i>		
Splenic infarction	1	0
Splenic vein thrombosis	1	0
<i><b>Thrombocytopenias</b></i>		
Immune thrombocytopenia	11	0
Thrombocytopenia	33	0
Thrombocytopenic purpura	2	0
<b>Blood disorders SOC TOTAL</b>	<b>2559</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	4	0
Bundle branch block left	1	0
Bundle branch block right	2	0
Sinoatrial block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	19	0
Cardiac dysfunction	3	0
Cardiac ventricular thrombosis	1	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	3	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	6	0
Palpitations	1763	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
Toxic cardiomyopathy	1	0
<i><b>Coronary artery disorders NEC</b></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><b>Heart failures NEC</b></i>		
Cardiac failure	8	0
Cardiac failure acute	1	0
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	2	0
Acute myocardial infarction	4	0
Angina pectoris	69	0
Angina unstable	3	0
Myocardial infarction	41	2
Myocardial ischaemia	1	0
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	1	0
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	8	0
Left ventricular dilatation	1	0
Left ventricular dysfunction	5	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	2	0
Myocardial injury	1	0
Myocardial oedema	2	0
<i><b>Noninfectious myocarditis</b></i>		

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Hypersensitivity myocarditis	1	0
Myocarditis	197	0
Myopericarditis	28	0
<b><i>Noninfectious pericarditis</i></b>		
Pericarditis	132	0
Pleuropericarditis	1	0
<b><i>Pericardial disorders NEC</i></b>		
Pericardial effusion	3	0
Pericardial rub	1	0
<b><i>Rate and rhythm disorders NEC</i></b>		
Arrhythmia	31	0
Bradycardia	15	0
Cardiac fibrillation	1	0
Cardiac flutter	141	0
Extrasystoles	56	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	4	0
Tachyarrhythmia	3	0
Tachycardia	775	1
Tachycardia foetal	1	0
<b><i>Supraventricular arrhythmias</i></b>		
Atrial fibrillation	47	0
Atrial flutter	13	0
Atrial tachycardia	3	0
Sinus arrhythmia	2	0
Sinus tachycardia	11	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	8	0
<b><i>Ventricular arrhythmias and cardiac arrest</i></b>		
Cardiac arrest	20	7
Ventricular arrhythmia	1	0
Ventricular extrasystoles	4	0
Ventricular fibrillation	1	0
Ventricular tachycardia	6	0
<b>Cardiac disorders SOC TOTAL</b>	<b>3479</b>	<b>12</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	3	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Gene mutations and other alterations NEC</i>		
Hereditary angioedema	1	0
<i>Haematological disorders congenital NEC</i>		
Neonatal alloimmune thrombocytopenia	1	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
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>14</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	8	0
Ear discomfort	9	0
Ear disorder	6	0
Ear inflammation	1	0
Ear pain	305	0
Ear swelling	6	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube obstruction	2	0
<i><b>External ear disorders NEC</b></i>		
Excessive cerumen production	3	0
Red ear syndrome	1	0
<i><b>External ear infections and inflammations</b></i>		
External ear inflammation	1	0
<i><b>Hearing losses</b></i>		
Deafness	55	0
Deafness neurosensory	2	0
Deafness transitory	1	0
Deafness unilateral	9	0
Hypoacusis	43	0
Sudden hearing loss	13	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	10	0
<i><b>Inner ear disorders NEC</b></i>		
Meniere's disease	1	0
Vestibular disorder	1	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	4	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	19	0
Tinnitus	460	0
Vertigo	316	0
Vertigo labyrinthine	2	0
Vertigo positional	15	0
<i><b>Middle ear infections and inflammations</b></i>		
Middle ear inflammation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>1295</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	2	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenal insufficiency	1	0
Adrenocortical insufficiency acute	6	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	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	2	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	4	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	5	0
<b>Endocrine disorders SOC TOTAL</b>	<b>60</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	4	0
<i><b>Cataract conditions</b></i>		
Cataract	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous detachment	2	0
Vitreous floaters	19	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	2	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	9	0
<i><b>Corneal infections, oedemas and inflammations</b></i>		
Ulcerative keratitis	1	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	35	0
Eyelid ptosis	4	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iridocyclitis	2	0
Iritis	2	0
Uveitis	11	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	37	0
Lacrimation increased	17	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	2	0
Erythema of eyelid	2	0
Eyelid cyst	1	0
Eyelid irritation	2	0
Eyelid oedema	2	0
Eyelid rash	2	0
Swelling of eyelid	33	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Lagophthalmos	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haematoma	1	0
Eye haemorrhage	4	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	5	0
Eye oedema	1	0
Eye pain	355	0
Eye swelling	133	0
Eyelid disorder	4	0
Eyelids pruritus	3	0
Ocular discomfort	16	0
Periorbital oedema	3	0
Periorbital swelling	22	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	5	0
Eye discharge	2	0
Eye inflammation	8	0
Eye irritation	20	0
Eye pruritus	40	0
Limbal swelling	1	0



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<b>Eye disorders</b> Eye disorders cont'd		
Ocular hyperaemia	47	0
<b>Ocular nerve and muscle disorders</b>		
Eye movement disorder	7	0
Gaze palsy	1	0
Ophthalmoplegia	1	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	2	0
Asthenopia	30	0
Foreign body sensation in eyes	8	0
Hypoaesthesia eye	6	0
Photophobia	133	0
<b>Optic disc abnormalities NEC</b>		
Optic discs blurred	1	0
Papilloedema	1	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic ischaemic neuropathy	1	0
<b>Orbital infections, inflammations and irritations</b>		
Orbital myositis	2	0
<b>Orbital structural change, deposit and degeneration</b>		
Lid sulcus deepened	2	0
<b>Pupil disorders</b>		
Mydriasis	5	0
<b>Refractive and accommodative disorders</b>		
Accommodation disorder	1	0
Astigmatism	3	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Papillophlebitis	1	0
Retinal haemorrhage	1	0
Retinal ischaemia	1	0
Retinal vein occlusion	11	0
<b>Retinal structural change, deposit and degeneration</b>		
Macular hole	1	0
Retinal detachment	1	0
<b>Retinal, choroid and vitreous infections and inflammations</b>		
Retinal oedema	1	0
<b>Retinopathies NEC</b>		
Acute macular neuroretinopathy	1	0
Central serous chorioretinopathy	4	0
Serous retinopathy	1	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	5	0
<b>Scleral structural change, deposit and degeneration</b>		
Scleral disorder	1	0
<b>Structural change, deposit and degeneration of eye NEC</b>		
Exophthalmos	2	0
<b>Visual colour distortions</b>		
Cyanopsia	1	0
Xanthopsia	2	0
<b>Visual disorders NEC</b>		
Diplopia	36	0
Halo vision	4	0
Metamorphopsia	5	0
Photopsia	32	0

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<b>Eye disorders</b> Eye disorders cont'd		
Scintillating scotoma	1	0
Vision blurred	323	0
<b>Visual field disorders</b>		
Visual field defect	5	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Amaurosis fugax	2	0
Blindness	42	0
Blindness transient	7	0
Blindness unilateral	2	0
Night blindness	1	0
Visual acuity reduced	3	0
Visual impairment	64	0
<b>Eye disorders SOC TOTAL</b>	<b>1626</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	4	0
Pancreatitis acute	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	9	0
<i>Anal and rectal signs and symptoms</i>		
Anal pruritus	1	0
Anal rash	1	0
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis	6	0
Colitis ischaemic	1	0
Colitis ulcerative	10	0
Crohn's disease	8	0
Inflammatory bowel disease	7	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	38	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1251	0
Diarrhoea haemorrhagic	6	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	162	0
Epigastric discomfort	4	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	81	0
Flatulence	42	0
<i>Gastric ulcers and perforation</i>		

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<b>Gastrointestinal disorders</b> Gastrointestinal disorders cont'd		
Gastric ulcer	2	0
Gastritis erosive	1	0
<b>Gastritis (excl infective)</b>		
Gastritis	12	0
<b>Gastrointestinal and abdominal pains (excl oral and throat)</b>		
Abdominal pain	359	0
Abdominal pain lower	27	0
Abdominal pain upper	921	0
Abdominal rigidity	3	0
Abdominal tenderness	5	0
Gastrointestinal pain	42	0
Oesophageal pain	1	0
<b>Gastrointestinal atonic and hypomotility disorders NEC</b>		
Constipation	44	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	40	0
<b>Gastrointestinal disorders NEC</b>		
Food poisoning	3	0
Functional gastrointestinal disorder	3	0
Gastric disorder	2	0
Gastrointestinal disorder	4	0
Lymphoid hyperplasia of intestine	1	0
Stomach mass	1	0
<b>Gastrointestinal dyskinetic disorders</b>		
Bowel movement irregularity	1	0
Change of bowel habit	3	0
Gastrointestinal motility disorder	2	0
Oesophageal achalasia	1	0
<b>Gastrointestinal inflammatory disorders NEC</b>		
Gastrointestinal inflammation	2	0
<b>Gastrointestinal mucosal dystrophies and secretion disorders</b>		
Hyperchlorhydria	2	0
<b>Gastrointestinal signs and symptoms NEC</b>		
Abdominal discomfort	184	0
Acute abdomen	1	0
Anal incontinence	3	0
Breath odour	8	0
Dysphagia	37	0
Odynophagia	8	0
<b>Gastrointestinal spastic and hypermotility disorders</b>		
Defaecation urgency	1	0
Frequent bowel movements	11	0
Irritable bowel syndrome	21	0
<b>Gastrointestinal stenosis and obstruction NEC</b>		
Intestinal obstruction	1	0
<b>Gastrointestinal vascular malformations</b>		
Gastric antral vascular ectasia	2	0
<b>Gastrointestinal vascular occlusion and infarction</b>		
Intestinal ischaemia	2	0
Mesenteric vein thrombosis	1	0
<b>Gingival disorders, signs and symptoms NEC</b>		
Gingival discomfort	2	0
Gingival disorder	3	0

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<b>Gastrointestinal disorders</b> Gastrointestinal disorders cont'd		
Gingival pain	24	0
Gingival swelling	8	0
Noninfective gingivitis	2	0
<b>Gingival haemorrhages</b>		
Gingival bleeding	14	0
<b>Haemorrhoids and gastrointestinal varices (excl oesophageal)</b>		
Haemorrhoids	6	0
<b>Intestinal haemorrhages</b>		
Anal haemorrhage	1	0
Rectal haemorrhage	19	0
<b>Malabsorption syndromes</b>		
Coeliac disease	1	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	1	0
Nausea	4922	0
Regurgitation	1	0
Retching	34	0
Vomiting	1908	0
Vomiting projectile	26	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	3	0
Haematemesis	8	0
Haematochezia	17	0
Melaena	1	0
Upper gastrointestinal haemorrhage	4	0
<b>Oesophageal disorders NEC</b>		
Oesophageal disorder	1	0
<b>Oesophagitis (excl infective)</b>		
Oesophagitis	1	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	2	0
Dry mouth	114	0
Lip dry	11	0
Saliva altered	2	0
Salivary hypersecretion	12	0
<b>Oral soft tissue disorders NEC</b>		
Chapped lips	3	0
Cheilitis	5	0
Enlarged uvula	1	0
Lip blister	4	0
Lip disorder	1	0
Oral disorder	1	0
Uvulitis	1	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	5	0
Oral blood blister	4	0
<b>Oral soft tissue signs and symptoms</b>		
Coating in mouth	2	0
Hypoaesthesia oral	93	0
Lip discolouration	1	0
Lip exfoliation	1	0
Lip pain	12	0
Lip pruritus	3	0

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<b>Gastrointestinal disorders</b> Gastrointestinal disorders cont'd		
Oral discomfort	13	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	38	0
Oral pruritus	2	0
Paraesthesia oral	132	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	1	0
Lip swelling	226	0
Mouth swelling	24	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	3	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Peritoneal and retroperitoneal fibrosis and adhesions</b>		
Retroperitoneal fibrosis	1	0
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland mass	1	0
Salivary gland pain	3	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	3	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	6	0
Lip ulceration	4	0
Mouth ulceration	102	0
Oral mucosa erosion	1	0
Stomatitis	6	0
<b>Tongue disorders</b>		
Glossitis	8	0
Tongue disorder	11	0
Tongue haemorrhage	1	0
Tongue ulceration	5	0
<b>Tongue signs and symptoms</b>		
Glossodynia	32	0
Stiff tongue	1	0
Swollen tongue	96	0
Tongue blistering	3	0
Tongue coated	5	0
Tongue discolouration	3	0
Tongue discomfort	7	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

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Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b> Gastrointestinal disorders cont'd		
Tongue rough	1	0
Tongue spasm	1	0
<i>Tooth missing</i>		
Tooth loss	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>11506</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	3	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
<b><i>Adverse effect absent</i></b>		
No adverse event	1	0
<b><i>Application and instillation site reactions</i></b>		
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	4	0
Application site pruritus	10	0
Application site rash	1	0
Application site reaction	1	0
Application site swelling	3	0
Application site vesicles	5	0
Application site warmth	2	0
Instillation site erythema	1	0
Instillation site warmth	5	0
<b><i>Asthenic conditions</i></b>		
Asthenia	670	0
Chronic fatigue syndrome	9	0
Decreased activity	1	0
Fatigue	6935	0
Malaise	1218	0
Sluggishness	2	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	2	0
Hypothermia	5	0
Temperature regulation disorder	3	0
<b><i>Complications associated with device NEC</i></b>		
Complication associated with device	1	0
Injury associated with device	1	0
<b><i>Death and sudden death</i></b>		
Cardiac death	2	2
Death	23	23
Sudden cardiac death	1	1
Sudden death	2	2
<b><i>Febrile disorders</i></b>		
Pyrexia	7080	1
<b><i>Feelings and sensations NEC</i></b>		
Chills	4322	0
Feeling abnormal	485	0
Feeling cold	455	0



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Feeling drunk	17	0
Feeling hot	389	0
Feeling jittery	13	0
Feeling of body temperature change	132	0
Hangover	21	0
Hunger	18	0
Sensation of blood flow	1	0
Sensation of foreign body	8	0
Temperature intolerance	22	0
Thirst	130	0
Thirst decreased	1	0
<b>Fibrosis NEC</b>		
Fibrosis	1	0
<b>Gait disturbances</b>		
Gait disturbance	44	0
Gait inability	26	0
Loss of control of legs	4	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	46	0
Crepitations	1	0
Crying	38	0
Discharge	4	0
Effusion	1	0
Energy increased	1	0
Exercise tolerance decreased	19	0
Foaming at mouth	2	0
General physical health deterioration	4	0
Glassy eyes	1	0
High-pitched crying	1	0
Illness	738	0
Induration	11	0
Influenza like illness	848	0
Irritability postvaccinal	1	0
Local reaction	29	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Perforation	1	0
Peripheral swelling	2259	0
Pre-existing disease	1	0
Screaming	8	0
Secretion discharge	2	0
Swelling	1275	0
Swelling face	219	0
<b>Implant and catheter site reactions</b>		
Catheter site related reaction	1	0
Implant site warmth	3	0
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	211	0
Scar inflammation	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	2	0
<b>Infusion site reactions</b>		

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<b>General disorders</b> General disorders cont'd		
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
Infusion site warmth	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	10	0
Injection site bruising	15	0
Injection site cyst	1	0
Injection site dermatitis	1	0
Injection site discolouration	1	0
Injection site erythema	223	0
Injection site haemorrhage	4	0
Injection site hypersensitivity	6	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site inflammation	20	0
Injection site irritation	3	0
Injection site joint erythema	5	0
Injection site joint pain	2	0
Injection site mass	215	0
Injection site movement impairment	1	0
Injection site nodule	1	0
Injection site oedema	6	0
Injection site pain	914	0
Injection site paraesthesia	2	0
Injection site plaque	1	0
Injection site pruritus	142	0
Injection site rash	213	0
Injection site reaction	25	0
Injection site swelling	122	0
Injection site urticaria	58	0
Injection site vesicles	3	0
Injection site warmth	103	0
<b>Interactions</b>		
Alcohol interaction	2	0
Drug interaction	3	0
Drug-device interaction	2	0
<b>Mass conditions NEC</b>		
Cyst	9	0
Mass	32	0
Nodule	6	0
<b>Mucosal findings abnormal</b>		
Enanthema	1	0
Mucosal discolouration	2	0
Mucosal inflammation	2	0
Mucosal pain	1	0
Oedema mucosal	1	0
Polyp	2	0
<b>Necrosis NEC</b>		
Necrosis	1	0
<b>Oedema NEC</b>		

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<b>General disorders</b> General disorders cont'd		
Face oedema	10	0
Localised oedema	7	0
Oedema	18	0
Oedema peripheral	16	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	922	0
Chest discomfort	480	0
Chest pain	1862	0
Discomfort	145	0
Facial discomfort	1	0
Facial pain	47	0
Hernia pain	1	0
Inflammatory pain	6	0
Non-cardiac chest pain	3	0
Pain	2835	0
Tenderness	209	0
Visceral pain	1	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	115	0
Adverse reaction	3	0
Drug ineffective	26	0
Drug intolerance	1	0
Immediate post-injection reaction	1	0
Inadequate analgesia	3	0
No reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	1	0
Therapeutic response changed	1	0
Therapeutic response unexpected	3	0
Treatment failure	1	0
Vaccination failure	13	0
<b><i>Ulcers NEC</i></b>		
Ulcer	5	0
<b><i>Vaccination site reactions</i></b>		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	15	0
Vaccination site bruising	28	0
Vaccination site discolouration	2	0
Vaccination site discomfort	9	0
Vaccination site eczema	1	0
Vaccination site erythema	313	0
Vaccination site haemorrhage	6	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	23	0
Vaccination site inflammation	22	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	3	0
Vaccination site macule	1	0
Vaccination site mass	85	0
Vaccination site movement impairment	23	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site oedema	1	0
Vaccination site pain	427	0
Vaccination site papule	2	0
Vaccination site paraesthesia	2	0
Vaccination site pruritus	75	0
Vaccination site rash	152	0
Vaccination site reaction	8	0
Vaccination site scar	1	0
Vaccination site swelling	212	0
Vaccination site urticaria	14	0
Vaccination site vesicles	3	0
Vaccination site warmth	147	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	1	0
Rebound effect	1	0
Withdrawal syndrome	7	0
<b>General disorders SOC TOTAL</b>	<b>38372</b>	<b>30</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	5	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	2	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	1	0
Jaundice	5	0
Jaundice cholestatic	2	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Hepatic cyst	1	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	2	0
Hypertransaminasaemia	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
Acute on chronic liver failure	1	0
<i><b>Hepatic vascular disorders</b></i>		
Portal vein thrombosis	2	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	13	0
Liver tenderness	2	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	3	0
Hepatic steatosis	1	0
Hepatitis	2	0
Immune-mediated hepatitis	1	0
Liver injury	4	0
<b>Hepatic disorders SOC TOTAL</b>	<b>49</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<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	365	0
Infusion related hypersensitivity reaction	14	0
Multiple allergies	4	0
Serum sickness	3	0
Serum sickness-like reaction	1	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	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	14	0
Drug hypersensitivity	15	0
Food allergy	4	0
Milk allergy	1	0
Perfume sensitivity	1	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	74	0
Anaphylactic shock	8	0
Anaphylactoid reaction	11	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	5	0
Immune-mediated adverse reaction	1	0
Immunisation reaction	25	0
Sensitisation	4	0
Systemic immune activation	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>651</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	10	0
Appendicitis perforated	1	0
Diverticulitis	5	0
Dysentery	1	0
Gastroenteritis	6	0
Peritonitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Administration site cellulitis	1	0
Application site cellulitis	1	0
Arthritis bacterial	1	0
Bacterial infection	3	0
Cellulitis	84	0
Folliculitis	1	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Paronychia	1	0
Skin bacterial infection	1	0
Vaccination site cellulitis	4	0
<b><i>Bone and joint infections</i></b>		
Arthritis infective	1	0
Osteomyelitis	1	0
<b><i>Borrelial infections</i></b>		
Relapsing fever	1	0
<b><i>Breast infections</i></b>		
Breast abscess	2	0
Mastitis	11	0
<b><i>Candida infections</i></b>		
Anal candidiasis	1	0
Candida infection	9	0
Oral candidiasis	7	0
Vulvovaginal candidiasis	11	0
<b><i>Cardiac infections</i></b>		
Endocarditis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Central nervous system infection	1	0
Encephalitis	4	0
Meningitis	6	0
Meningitis aseptic	1	0
Myelitis	1	0
<b><i>Chlamydial infections</i></b>		
Eye infection chlamydial	1	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	1	0
COVID-19	411	0
COVID-19 pneumonia	6	0
Coronavirus infection	1	0
Post-acute COVID-19 syndrome	6	0
Suspected COVID-19	5	0
<b><i>Coxiella infections</i></b>		
Q fever	8	0
<b><i>Cytomegaloviral infections</i></b>		
Cytomegalovirus infection	2	0

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Cytomegalovirus infection reactivation	2	0
Pneumonia cytomegaloviral	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	2	0
Oral infection	1	0
Sialoadenitis	2	0
Tooth abscess	2	0
Tooth infection	2	0
<b><i>Ear infections</i></b>		
Ear infection	10	0
Labyrinthitis	15	0
Otitis externa	1	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	1	0
Lice infestation	1	0
<b><i>Enteroviral infections NEC</i></b>		
Hand-foot-and-mouth disease	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	2	0
<b><i>Eye and eyelid infections</i></b>		
Chorioretinitis	1	0
Conjunctivitis	13	0
Eye infection	4	0
Eyelid boil	1	0
Eyelid infection	1	0
Hordeolum	5	0
<b><i>Female reproductive tract infections</i></b>		
Vaginal infection	1	0
<b><i>Flaviviral infections</i></b>		
Dengue fever	2	0
Encephalitis Japanese B	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	4	0
Fungal skin infection	3	0
Overgrowth fungal	1	0
Pneumonia fungal	1	0
<b><i>Fusobacterium infections</i></b>		
Necrotising ulcerative gingivostomatitis	1	0
<b><i>Helicobacter infections</i></b>		
Helicobacter infection	1	0
<b><i>Hepatitis virus infections</i></b>		
Hepatitis A	1	0
<b><i>Herpes viral infections</i></b>		
Eczema herpeticum	1	0
Genital herpes	15	0
Herpes ophthalmic	2	0
Herpes simplex	8	0
Herpes simplex reactivation	1	0
Herpes virus infection	1	0
Herpes zoster	133	0
Herpes zoster oticus	3	0
Nasal herpes	1	0



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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	98	0
Varicella	3	0
Varicella zoster virus infection	1	0
<b><i>Infections NEC</i></b>		
Abscess	2	0
Abscess limb	2	0
Abscess rupture	1	0
Empyema	1	1
Groin infection	1	0
Infection	96	0
Injection site infection	1	0
Localised infection	19	0
Lymph gland infection	2	0
Lymph node abscess	3	0
Respiratory tract infection	2	0
Vaccination site abscess	2	0
Vaccination site infection	5	0
Vaccine breakthrough infection	1	0
Vestibulitis	1	0
Wound infection	1	0
<b><i>Infectious disorders carrier</i></b>		
SARS-CoV-2 carrier	2	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	626	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Atypical pneumonia	1	0
Bronchitis	6	0
Lower respiratory tract infection	86	1
Pleural infection	1	0
Pneumonia	24	5
Pneumonia aspiration	1	0
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	1	0
Orchitis	3	0
<b><i>Mumps viral infections</i></b>		
Mumps	1	0
<b><i>Nematode infections</i></b>		
Enterobiasis	1	0
<b><i>Orthopox viral infections</i></b>		
Vaccinia virus infection	1	0
<b><i>Parvoviral infections</i></b>		
Erythema infectiosum	1	0
<b><i>Rabies viral infections</i></b>		
Rabies	1	1
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
<b><i>Rubella viral infections</i></b>		
Rubella	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Intestinal sepsis	1	0
Sepsis	8	0
Septic shock	1	0
Urosepsis	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
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	15	0
Vaccination site pustule	1	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	11	0
<b><i>Streptococcal infections</i></b>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	1	0
<b><i>Tinea infections</i></b>		
Body tinea	3	0
Tinea capitis	1	0
Tinea infection	1	0
<b><i>Tuberculous infections</i></b>		
Lymph node tuberculosis	1	0
<b><i>Upper respiratory tract infections</i></b>		
Acute sinusitis	2	0
Chronic sinusitis	1	0
Laryngitis	7	0
Nasopharyngitis	331	0
Peritonsillar abscess	1	0
Pharyngitis	6	0
Rhinitis	8	0
Sinusitis	38	0
Tonsillitis	15	0
Upper respiratory tract infection	3	0
<b><i>Urinary tract infections</i></b>		
Cystitis	12	0
Kidney infection	6	0
Urinary tract infection	43	0
<b><i>Vascular infections</i></b>		
Lymphangitis	3	0
<b><i>Viral infections NEC</i></b>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Gastroenteritis viral	4	0
Meningitis viral	2	0
Pneumonia viral	2	0
Post viral fatigue syndrome	8	0
Sweating fever	64	0
Vestibular neuronitis	4	0
Viral infection	10	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Viral labyrinthitis	2	0
Viral myocarditis	1	0
Viral pharyngitis	6	0
Viral rash	7	0
<b>Infections SOC TOTAL</b>	<b>2538</b>	<b>8</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Oral contusion	1	0
Palate injury	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	2	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Anaesthetic complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotrauma	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Joint injury	3	0
<b><i>Cardiovascular injuries</i></b>		
Vascular injury	1	0
<b><i>Cerebral injuries NEC</i></b>		
Concussion	8	0
Subdural haematoma	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	3	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	18	0
<b><i>Cranial nerve injuries</i></b>		
Cranial nerve injury	1	0
Optic nerve injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	25	0
Foetal exposure during pregnancy	11	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	595	0
Maternal exposure during pregnancy	274	0
Maternal exposure timing unspecified	1	0
<b><i>Exposures to agents or circumstances NEC</i></b>		
Exposure to SARS-CoV-2	3	0
<b><i>Eye injuries NEC</i></b>		
Blindness traumatic	1	0
Eye contusion	2	0
Eye injury	7	0
<b><i>Fractures and dislocations NEC</i></b>		
Compression fracture	1	0
Joint dislocation	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Procedural vomiting	1	0
<b><i>Heat injuries (excl thermal burns)</i></b>		
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	9	0
Heat stroke	9	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	8	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Circumstance or information capable of leading to medication error	6	0
Medication error	47	0
Wrong schedule	1	0
Wrong technique in device usage process	2	0

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Wrong technique in product usage process	1	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	3	0
Ligament sprain	2	0
Muscle injury	6	0
Muscle rupture	1	0
Muscle strain	5	0
Tendon injury	2	0
Tendon rupture	1	0
<b>Nerve injuries NEC</b>		
Nerve injury	23	0
Nerve root injury lumbar	1	0
<b>Neurological and psychiatric procedural complications</b>		
Procedural dizziness	5	0
<b>Non-occupational environmental exposures</b>		
Exposure to extreme temperature	1	0
<b>Non-site specific injuries NEC</b>		
Arthropod bite	5	0
Bite	1	0
Electric shock	6	0
Fall	61	0
Inflammation of wound	2	0
Injury	5	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
<b>Non-site specific procedural complications</b>		
Incision site pain	1	0
Infusion related reaction	1	0
Injection related reaction	38	0
Post procedural complication	1	0
Post procedural erythema	1	0
Procedural pain	1	0
<b>Occupational exposures</b>		
Occupational exposure to toxic agent	1	0
<b>Off label uses</b>		
Off label use	29	0
<b>Overdoses NEC</b>		
Overdose	6	0
<b>Peripheral nerve injuries</b>		
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
<b>Poisoning and toxicity</b>		
Systemic toxicity	1	0
Toxicity to various agents	1	0
<b>Product administration errors and issues</b>		
Accidental overdose	73	0
Accidental underdose	2	0
Expired product administered	61	0
Extra dose administered	67	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Inappropriate schedule of product administration	101	0
Inappropriate schedule of product discontinuation	1	0
Incorrect dose administered	14	0
Incorrect product administration duration	1	0
Incorrect route of product administration	3	0
Poor quality product administered	2	0
Product administered at inappropriate site	6	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product administration interrupted	1	0
Product dose omission issue	5	0
Wrong product administered	3	0
<b>Product confusion errors and issues</b>		
Product label confusion	11	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	1	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	1	0
<b>Product selection errors and issues</b>		
Product selection error	7	0
<b>Product transcribing errors and communication issues</b>		
Product communication issue	1	0
<b>Radiation injuries</b>		
Sunburn	15	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
<b>Respiratory tract and thoracic cavity procedural complications</b>		
Post procedural pulmonary embolism	1	0
<b>Site specific injuries NEC</b>		
Back injury	2	0
Head injury	10	0
Limb injury	54	0
Nasal injury	1	0
<b>Skin injuries NEC</b>		
Contusion	350	0
Scar	12	0
Scratch	2	0
Skin abrasion	1	0
Skin injury	1	0
Skin laceration	1	0
Skin wound	3	0
Subcutaneous haematoma	2	0
<b>Skin procedural complications</b>		
Dermal filler reaction	1	0
<b>Skull fractures, facial bone fractures and dislocations</b>		
Jaw fracture	1	0
<b>Spinal cord injuries NEC</b>		
Spinal cord injury cervical	1	0
<b>Stoma complications</b>		
Stoma site discomfort	1	0
Stoma site oedema	1	0
<b>Thermal burns</b>		
Burn oesophageal	1	0

# Case Series Drug Analysis Print

## Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Cold burn	1	0
Thermal burn	14	0
Thermal burns of eye	6	0
<b><i>Thoracic cage fractures and dislocations</i></b>		
Sternal fracture	1	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	2	0
<b>Injuries SOC TOTAL</b>	<b>2126</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b>Adrenal medulla tests</b>		
Norepinephrine increased	2	0
<b>Auditory and vestibular diagnostic procedures</b>		
Audiogram abnormal	1	0
<b>Autoimmunity analyses</b>		
Rheumatoid factor increased	1	0
<b>Bacteria identification and serology (excl mycobacteria)</b>		
Campylobacter test positive	1	0
<b>Blood counts NEC</b>		
Full blood count abnormal	1	0
<b>Blood gas and acid base analyses</b>		
Blood lactic acid	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	3	0
Oxygen saturation decreased	20	0
<b>Carbohydrate tolerance analyses (incl diabetes)</b>		
Blood glucose	1	0
Blood glucose abnormal	1	0
Blood glucose decreased	3	0
Blood glucose increased	7	0
<b>Cardiac auscultatory investigations</b>		
Cardiac murmur	4	0
Heart sounds	5	0
<b>Cardiac function diagnostic procedures</b>		
Ejection fraction decreased	1	0
<b>Central nervous system imaging procedures</b>		
Computerised tomogram head	1	0
<b>Chemistry analyses NEC</b>		
Histamine abnormal	1	0
<b>Cholesterol analyses</b>		
Blood cholesterol increased	2	0
Low density lipoprotein increased	1	0
<b>Coagulation and bleeding analyses</b>		
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	2	0
<b>Digestive enzymes</b>		
Amylase increased	1	0
<b>ECG investigations</b>		
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
<b>Endocrine analyses and imaging NEC</b>		



## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Hormone level abnormal	16	0
<b>Fertility analyses</b>		
Semen analysis abnormal	1	0
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate decreased	1	0
Foetal heart rate increased	1	0
<b>Fungus identification and serology</b>		
Fungal test	1	0
<b>Gastrointestinal and abdominal imaging procedures</b>		
X-ray with contrast upper gastrointestinal tract	1	0
<b>Gastrointestinal function diagnostic procedures</b>		
Gastric pH decreased	1	0
<b>Haematological analyses NEC</b>		
Blood viscosity increased	1	0
<b>Heart rate and pulse investigations</b>		
Heart rate	275	0
Heart rate abnormal	22	0
Heart rate decreased	18	0
Heart rate increased	418	0
Heart rate irregular	92	0
Heart rate variability decreased	1	0
Maximum heart rate	1	0
Maximum heart rate increased	1	0
Pulse abnormal	2	0
Pulse absent	1	0
Sinus rhythm	3	0
<b>Hepatobiliary function diagnostic procedures</b>		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase	2	0
Bile output	3	0
Blood bilirubin increased	1	0
Liver function test abnormal	8	0
Liver function test increased	1	0
<b>Imaging procedures NEC</b>		
X-ray	1	0
<b>Immunology analyses NEC</b>		
Immunology test	1	0
<b>Immunology skin tests NEC</b>		
Allergy alert test	1	0
Allergy alert test positive	1	0
<b>Investigations NEC</b>		
Blood test	1	0
Blood test abnormal	5	0
Blood test normal	2	0
Polymerase chain reaction positive	2	0
<b>Mineral and electrolyte analyses</b>		
Blood calcium increased	2	0
Blood iron	1	0
Blood iron decreased	3	0
Blood magnesium decreased	1	0
Blood potassium decreased	3	0
Blood sodium decreased	1	0
Serum ferritin increased	2	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Urine copper	1	0
<b>Musculoskeletal and soft tissue imaging procedures</b>		
Bone scan	1	0
Face and mouth X-ray abnormal	1	0
<b>Musculoskeletal and soft tissue tests NEC</b>		
Tender joint count	1	0
<b>Neurologic diagnostic procedures</b>		
Coma scale abnormal	2	0
Electromyogram abnormal	1	0
Sensory level	1	0
<b>Ophthalmic function diagnostic procedures</b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
Visual tracking test	1	0
Visual tracking test abnormal	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature	106	0
Body temperature abnormal	12	0
Body temperature decreased	18	0
Body temperature fluctuation	27	0
Body temperature increased	140	0
Breath sounds	1	0
Breath sounds abnormal	1	0
Grip strength	1	0
Grip strength decreased	3	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	5	0
Respiratory rate decreased	6	0
Respiratory rate increased	10	0
Skin temperature	24	0
Temperature difference of extremities	6	0
Weight decreased	28	0
Weight increased	11	0
<b>Pituitary analyses anterior</b>		
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
<b>Platelet analyses</b>		
Platelet count decreased	10	0
Platelet count normal	1	0
<b>Protein analyses NEC</b>		
C-reactive protein increased	9	0
<b>Red blood cell analyses</b>		
Haemoglobin E	1	0
Haemoglobin decreased	2	0
<b>Renal function analyses</b>		
Blood creatinine increased	1	0
<b>Reproductive hormone analyses</b>		
Blood testosterone decreased	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
False negative pregnancy test	1	0
Pregnancy test	1	0
Pregnancy test false positive	1	0
<b>Reproductive organ and breast histopathology procedures</b>		
Smear cervix	1	0
<b>Reproductive organ and breast imaging procedures</b>		
Hysteroscopy	1	0
<b>Respiratory and pulmonary function diagnostic procedures</b>		
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	3	0
Pulmonary function test decreased	1	0
<b>Skeletal and cardiac muscle analyses</b>		
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
<b>Therapeutic drug monitoring analyses</b>		
Analgesic drug level	5	0
<b>Thyroid analyses</b>		
Tri-iodothyronine decreased	1	0
<b>Tissue enzyme analyses NEC</b>		
Blood alkaline phosphatase increased	1	0
Blood lactate dehydrogenase increased	1	0
<b>Urinalysis NEC</b>		
Blood urine	5	0
Blood urine present	27	0
Protein urine	1	0
pH urine	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output	12	0
Urine output decreased	1	0
<b>Urinary tract imaging procedures</b>		
Bladder scan	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	2	0
Blood pressure decreased	11	0
Blood pressure diastolic increased	1	0
Blood pressure increased	42	0
Blood pressure measurement	10	0
Blood pressure normal	1	0
<b>Virus identification and serology</b>		
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	5	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	7	0
<b>Vitamin analyses</b>		
Blood folate decreased	1	0
<b>White blood cell analyses</b>		

# Case Series Drug Analysis Print

## Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
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	2	0
<b>Investigations SOC TOTAL</b>	<b>1618</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	3	0
Decreased appetite	456	0
Eating disorder symptom	1	0
Food craving	2	0
Food refusal	4	0
Hyperphagia	5	0
Hypophagia	3	0
Increased appetite	9	0
Salt craving	1	0
<b><i>Copper metabolism disorders</i></b>		
Copper deficiency	1	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Diabetes mellitus	5	0
Diabetes mellitus inadequate control	4	0
Type 1 diabetes mellitus	1	0
Type 2 diabetes mellitus	1	0
<b><i>Diabetic complications NEC</i></b>		
Diabetic ketoacidosis	2	0
<b><i>Disorders of purine metabolism</i></b>		
Gout	23	0
<b><i>Fat soluble vitamin deficiencies and disorders</i></b>		
Vitamin D deficiency	1	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	1	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	1	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Alcohol intolerance	2	0
Food intolerance	3	0
Gluten sensitivity	1	0
Histamine intolerance	1	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal loss of weight	6	0
Abnormal weight gain	9	0
Feeding disorder	55	0
Food aversion	5	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	1	0
Weight loss poor	1	0
<b><i>Hyperglycaemic conditions NEC</i></b>		
Hyperglycaemia	7	0
<b><i>Hypoglycaemic conditions NEC</i></b>		
Hypoglycaemia	10	0
<b><i>Iron excess</i></b>		
Haemochromatosis	1	0
<b><i>Potassium imbalance</i></b>		
Hypokalaemia	2	0
<b><i>Sodium imbalance</i></b>		
Hyponatraemia	1	0
<b><i>Sugar intolerance (excl glucose intolerance)</i></b>		
Lactose intolerance	1	0

# Case Series Drug Analysis Print

## Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
<i>Total fluid volume decreased</i>		
Dehydration	107	0
<i>Total fluid volume increased</i>		
Fluid retention	11	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>755</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	65	0
Arthritis allergic	1	0
Arthritis enteropathic	1	0
Arthropathy	9	0
Autoimmune arthritis	1	0
Palindromic rheumatism	1	0
Polyarthrits	2	0
<b><i>Bone disorders NEC</i></b>		
Bone erosion	1	0
Exostosis	2	0
Jaw cyst	1	0
Jaw disorder	2	0
Medial tibial stress syndrome	1	0
Osteitis	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	121	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	108	0
Pubic pain	1	0
Spinal pain	19	0
<b><i>Bursal disorders</i></b>		
Bursitis	24	0
<b><i>Cartilage disorders</i></b>		
Chondritis	1	0
Costochondritis	23	0
<b><i>Connective tissue disorders NEC</i></b>		
Morphoea	1	0
Polymyalgia rheumatica	7	0
Reynold's syndrome	2	0
<b><i>Extremity deformities</i></b>		
Finger deformity	1	0
Foot deformity	2	0
Hand deformity	2	0
<b><i>Intervertebral disc disorders NEC</i></b>		
Intervertebral disc protrusion	2	0
<b><i>Joint related disorders NEC</i></b>		
Greater trochanteric pain syndrome	1	0
Hypermobility syndrome	1	0
Joint lock	12	0
Periarthritis	57	0
Rotator cuff syndrome	7	0
Temporomandibular joint syndrome	2	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	2684	0
Joint effusion	1	0
Joint noise	4	0
Joint range of motion decreased	1	0
Joint stiffness	83	0
Joint swelling	93	0
Joint vibration	2	0
Joint warmth	7	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b> Muscle & tissue disorders cont'd		
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
<i>Muscle infections and inflammations</i>		
Myositis	10	0
<i>Muscle pains</i>		
Fibromyalgia	27	0
Myalgia	3472	0
Myalgia intercostal	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	3	0
Muscle discomfort	3	0
Muscle disorder	1	0
Muscle fatigue	117	0
Muscle haemorrhage	1	0
Muscle spasms	520	0
Muscle swelling	17	0
Muscle tightness	32	0
Muscle twitching	94	0
Myosclerosis	1	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	5	0
Nuchal rigidity	5	0
Trismus	11	0
<i>Muscle weakness conditions</i>		
Muscular weakness	274	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Limb mass	3	0
Mastication disorder	2	0
Mobility decreased	33	0
Muscle contracture	1	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	503	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
Plantar fasciitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	868	0
Flank pain	19	0
Limb discomfort	414	0
Musculoskeletal chest pain	69	0
Musculoskeletal discomfort	31	0
Musculoskeletal pain	26	0
Neck pain	514	0
Pain in extremity	4128	1
Sacral pain	1	0
<i>Myopathies</i>		



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Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b> Muscle & tissue disorders cont'd		
Rhabdomyolysis	1	0
<b>Osteoarthropathies</b>		
Osteoarthritis	6	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	4	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	24	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	59	0
Fluctuance	1	0
Groin pain	27	0
Neck mass	14	0
Soft tissue swelling	2	0
<b>Spine and neck deformities</b>		
Spinal stenosis	1	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	4	0
Arthritis reactive	19	0
Axial spondyloarthritis	1	0
Spondylitis	1	0
<b>Synovial disorders</b>		
Synovial cyst	5	0
Synovitis	2	0
<b>Tendon disorders</b>		
Tendon pain	4	0
Tendonitis	8	0
Trigger finger	3	0
<b>Trunk deformities</b>		
Shoulder deformity	2	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>14768</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i><b>B-cell lymphomas NEC</b></i>		
B-cell lymphoma stage II	1	0
B-cell lymphoma stage III	1	0
<i><b>Breast and nipple neoplasms benign</b></i>		
Benign breast neoplasm	2	0
Fibroadenoma of breast	1	0
<i><b>Breast and nipple neoplasms malignant</b></i>		
Breast cancer	4	0
<i><b>Breast neoplasms unspecified malignancy</b></i>		
Phyllodes tumour	1	0
<i><b>Cardiovascular neoplasms benign</b></i>		
Haemangioma	1	0
<i><b>Leukaemias NEC</b></i>		
Leukaemia	1	0
<i><b>Lymphomas unspecified NEC</b></i>		
Lymphoma	9	0
<i><b>Mediastinal neoplasms malignancy unspecified NEC</b></i>		
Good syndrome	1	0
<i><b>Metastases to specified sites</b></i>		
Metastases to lymph nodes	1	0
<i><b>Metastases to unknown and unspecified sites</b></i>		
Metastasis	1	0
<i><b>Neoplasms malignant site unspecified NEC</b></i>		
Neoplasm malignant	1	0
<i><b>Oesophageal neoplasms malignant</b></i>		
Oesophageal carcinoma	1	0
<i><b>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</b></i>		
Tonsil cancer	2	0
<i><b>Plasma cell neoplasms NEC</b></i>		
Hypergammaglobulinaemia benign monoclonal	1	0
<i><b>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</b></i>		
Bronchial carcinoma	1	0
<i><b>Skin neoplasms benign</b></i>		
Acrochordon	2	0
Anogenital warts	1	0
Haemangioma of skin	3	0
Melanocytic naevus	1	0
Skin papilloma	4	0
<i><b>Skin neoplasms malignant and unspecified (excl melanoma)</b></i>		
Keratoacanthoma	1	0
<i><b>Small intestinal neoplasms malignant</b></i>		
Small intestine adenocarcinoma	1	0
Small intestine carcinoma	1	0
<i><b>Soft tissue neoplasms benign NEC</b></i>		
Lipoma	2	0
<i><b>Urinary tract neoplasms unspecified malignancy NEC</b></i>		
Renal neoplasm	1	0
<i><b>Uterine neoplasms benign</b></i>		
Uterine leiomyoma	3	0
<i><b>Uterine neoplasms malignant NEC</b></i>		
Uterine cancer	1	0

# Case Series Drug Analysis Print

## Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Neoplasms SOC TOTAL	51	0

## Case Series Drug Analysis Print

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Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Abnormal sleep-related events</i></b>		
Sleep paralysis	5	0
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	1	0
<b><i>Acute polyneuropathies</i></b>		
Guillain-Barre syndrome	20	0
<b><i>Autonomic nervous system disorders</i></b>		
Autonomic nervous system imbalance	2	0
Orthostatic intolerance	3	0
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Brain stem infarction	1	0
Cerebral artery embolism	1	0
Cerebral haemorrhage	4	2
Cerebral infarction	1	0
Cerebrovascular accident	44	2
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	0
Intracranial haematoma	1	0
Intraventricular haemorrhage	1	0
Ischaemic stroke	5	0
Lacunar infarction	1	0
Ruptured cerebral aneurysm	1	1
Subarachnoid haemorrhage	7	0
<b><i>Central nervous system inflammatory disorders NEC</i></b>		
Central nervous system inflammation	2	0
<b><i>Central nervous system vascular disorders NEC</i></b>		
Cerebral congestion	2	0
<b><i>Cerebrovascular venous and sinus thrombosis</i></b>		
Cerebral venous sinus thrombosis	4	0
Cerebral venous thrombosis	1	0
<b><i>Cervical spinal cord and nerve root disorders</i></b>		
Cervical radiculopathy	1	0
<b><i>Choreiform movements</i></b>		
Chorea	1	0
<b><i>Chronic polyneuropathies</i></b>		
Chronic inflammatory demyelinating polyradiculoneuropathy	3	0
Demyelinating polyneuropathy	1	0
<b><i>Coordination and balance disturbances</i></b>		
Ataxia	5	0
Balance disorder	106	0
Coordination abnormal	7	0
Dysstasia	19	0
Nystagmus	3	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	10	0
Dysgraphia	1	0
<b><i>Cranial nerve disorders NEC</i></b>		
Cranial nerve disorder	1	0
<b><i>Dementia (excl Alzheimer's type)</i></b>		
Dementia	3	0
<b><i>Demyelinating disorders NEC</i></b>		
Demyelination	2	0
<b><i>Disturbances in consciousness NEC</i></b>		

## Case Series Drug Analysis Print

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Report Run Date: 16-Jun-2022

Data Lock Date: 15-Jun-2022 18:30:06

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
Consciousness fluctuating	1	0
Depressed level of consciousness	16	0
Lethargy	553	0
Loss of consciousness	290	0
Postictal state	1	0
Somnolence	296	0
Stupor	1	0
Syncope	1164	0
<b><i>Disturbances in sleep phase rhythm</i></b>		
Delayed sleep phase	1	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Akathisia	2	0
Bradykinesia	5	0
Clumsiness	4	0
Dyskinesia	17	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	23	0
Motor dysfunction	3	0
Movement disorder	13	0
Psychomotor hyperactivity	5	0
<b><i>Dystonias</i></b>		
Dystonia	1	0
<b><i>Encephalitis NEC</i></b>		
Encephalitis allergic	1	0
Noninfective encephalitis	1	0
<b><i>Eye movement disorders</i></b>		
IVth nerve paresis	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Bell's palsy	105	0
Facial nerve disorder	1	0
Facial paralysis	59	0
Facial paresis	12	0
Facial spasm	7	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	11	0
<b><i>Glossopharyngeal nerve disorders</i></b>		
Glossopharyngeal neuralgia	1	0
<b><i>Headaches NEC</i></b>		
Cluster headache	66	0
Cold-stimulus headache	12	0
Drug withdrawal headache	2	0
Headache	8614	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	110	0
Tension headache	173	0

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
Thunderclap headache	3	0
Vascular headache	7	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	1	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	3	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	16	0
<b>Memory loss (excl dementia)</b>		
Amnesia	63	0
Memory impairment	42	0
Transient global amnesia	2	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	27	0
Disturbance in attention	93	0
Mental impairment	18	0
<b>Migraine headaches</b>		
Basilar migraine	1	0
Hemiplegic migraine	7	0
Migraine	860	0
Migraine with aura	50	0
Migraine without aura	3	0
Retinal migraine	5	0
Typical aura without headache	1	0
Vestibular migraine	4	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	6	0
Cubital tunnel syndrome	1	0
Mononeuritis	2	0
Nerve compression	4	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0
Multiple sclerosis	5	0
Multiple sclerosis pseudo relapse	1	0
Multiple sclerosis relapse	6	0
Progressive multiple sclerosis	1	0
Uhthoff's phenomenon	1	0
<b>Muscle tone abnormal</b>		
Drop attacks	1	0
Hypotonia	10	0
Stiff leg syndrome	3	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	7	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	32	0
Narcolepsy	1	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	5	0
Psychomotor skills impaired	1	0
<b>Neurologic visual problems NEC</b>		

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Report Run Date: 16-Jun-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
Hemianopia	1	0
Tunnel vision	13	0
<b>Neurological signs and symptoms NEC</b>		
Agitation neonatal	1	0
Clonus	2	0
Dizziness	3456	0
Dizziness exertional	14	0
Dizziness postural	230	0
Drooling	2	0
Exaggerated startle response	1	0
Head discomfort	71	0
Meningism	1	0
Neurological symptom	13	0
Persistent postural-perceptual dizziness	3	0
Presyncope	265	0
Tongue biting	2	0
Unresponsive to stimuli	13	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	2	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	39	0
Hyposmia	2	0
Parosmia	49	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	5	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	7	0
Burning sensation	135	0
Dysaesthesia	1	0
Formication	8	0
Hemianaesthesia	1	0
Hemihypoaesthesia	1	0
Hyperaesthesia	57	0
Hypoaesthesia	696	0
Paraesthesia	1006	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	6	0
Hemiparesis	6	0
Hemiplegia	12	0
Monoparesis	25	0
Monoplegia	30	0
Paralysis	37	0
Paraparesis	2	0
Paresis	2	0
Quadriplegia	1	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	12	0
Reduced facial expression	1	0
<b>Partial complex seizures</b>		

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
Focal dyscognitive seizures	2	0
<b>Peripheral neuropathies NEC</b>		
Autoimmune neuropathy	2	0
Neuralgic amyotrophy	4	0
Neuritis	3	0
Neuropathy peripheral	14	0
Peripheral sensory neuropathy	1	0
Polyneuropathy	2	0
<b>Seizures and seizure disorders NEC</b>		
Atonic seizures	1	0
Epilepsy	27	0
Febrile convulsion	6	0
Myoclonic epilepsy	1	0
Partial seizures	8	0
Psychogenic seizure	1	0
Seizure	216	0
Seizure anoxic	2	0
Seizure cluster	1	0
Status epilepticus	29	0
Tonic clonic movements	3	0
Tonic convulsion	5	0
<b>Sensory abnormalities NEC</b>		
Ageusia	94	0
Allodynia	3	0
Aura	4	0
Complex regional pain syndrome	1	0
Dysgeusia	236	0
Electric shock sensation	15	0
Hypogeusia	1	0
Neuralgia	157	0
Post herpetic neuralgia	3	0
Restless legs syndrome	48	0
Sensory disturbance	29	0
Sensory loss	36	0
Taste disorder	54	0
Vibratory sense increased	2	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	6	0
<b>Speech and language abnormalities</b>		
Dysarthria	45	0
Incoherent	12	0
Slow speech	5	0
Speech disorder	20	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radicular pain	1	0
Radiculitis brachial	3	0
Radiculopathy	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	26	0
<b>Tremor (excl congenital)</b>		
Essential tremor	2	0
Head titubation	2	0
Tremor	738	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> Nervous system disorders cont'd		
<i>Trigeminal disorders</i>		
Trigeminal neuralgia	11	0
Trigeminal neuritis	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>21278</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	71	0
<i><b>Foetal complications NEC</b></i>		
Foetal hypokinesia	4	0
Hydrops foetalis	1	0
<i><b>Foetal growth complications</b></i>		
Foetal growth restriction	2	0
<i><b>Gestational age and weight conditions</b></i>		
Premature baby	2	0
<i><b>Haemorrhagic complications of pregnancy</b></i>		
Premature separation of placenta	1	0
Subchorionic haemorrhage	1	0
<i><b>Labour onset and length abnormalities</b></i>		
Premature labour	5	0
<i><b>Maternal complications of labour NEC</b></i>		
Uterine atony	1	0
Uterine hypertonus	3	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Decidual cast	1	0
Ectopic pregnancy	3	0
Morning sickness	1	0
Somatic symptom disorder of pregnancy	1	0
Uterine irritability	1	0
<i><b>Multiple pregnancies</b></i>		
Twin pregnancy	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Live birth	2	0
Pregnancy	4	0
<i><b>Postpartum complications NEC</b></i>		
Postpartum haemorrhage	1	0
<i><b>Pregnancy complicated by maternal disorders</b></i>		
Gestational diabetes	1	0
<i><b>Stillbirth and foetal death</b></i>		
Stillbirth	1	1
<i><b>Umbilical cord complications</b></i>		
Umbilical cord thrombosis	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>109</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device expulsion	1	0
Device leakage	1	0
<b><i>Device malfunction events NEC</i></b>		
Oversensing	1	0
Thrombosis in device	2	0
Undersensing	2	0
<b><i>Manufacturing materials issues</i></b>		
Manufacturing materials issue	1	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination physical	8	0
Suspected product contamination	1	0
<b><i>Product label issues</i></b>		
Product label issue	3	0
<b><i>Product physical issues</i></b>		
Product after taste	1	0
Product taste abnormal	1	0
<b><i>Product quality issues NEC</i></b>		
Product complaint	1	0
Product impurity	1	0
Product quality issue	1	0
Product tampering	1	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	2	0
<b>null SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	6	0
Breath holding	4	0
Staring	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	2	0
Constricted affect	2	0
Flat affect	4	0
Inappropriate affect	3	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	2	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	1	0
Separation anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	26	0
Anxiety	266	0
Nervousness	51	0
Stress	24	0
Tension	10	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	5	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	2	0
Disinhibition	1	0
Homicidal ideation	1	0
Impatience	1	0
Paranoia	7	0
Personality change	3	0
Social avoidant behaviour	1	0
Violence-related symptom	1	0
<b><i>Bipolar disorders</i></b>		
Bipolar disorder	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Distractibility	1	0
Mental fatigue	63	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	242	0
Disorientation	97	0
<b><i>Deliria</i></b>		
Delirium	61	0
<b><i>Delusional disorders</i></b>		
Alice in wonderland syndrome	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	3	0
Delusion of parasitosis	1	0
<b><i>Depressive disorders</i></b>		
Depression	102	0
Depression suicidal	4	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	3	0
Dissociation	13	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	7	0
Insomnia	521	0
Middle insomnia	14	0
Terminal insomnia	13	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	103	0
<b><i>Eating disorders NEC</i></b>		
Binge eating	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	15	0
Emotional disorder	21	0
Emotional distress	12	0
Emotional poverty	1	0
Euphoric mood	12	0
Frustration tolerance decreased	4	0
Irritability	55	0
Mood altered	21	0
<b><i>Factitious disorders</i></b>		
Factitious disorder	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	7	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
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	18	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	136	0
Hallucination, auditory	6	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	6	0
Hallucinations, mixed	3	0
Somatic hallucination	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	62	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	4	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	2	0
Depressed mood	99	0
Feeling of despair	5	0
Negative thoughts	2	0
Sense of a foreshortened future	1	0
Tearfulness	7	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
<b><i>Mood alterations with manic symptoms</i></b>		
Mania	5	0
<b><i>Mood disorders NEC</i></b>		
Affective disorder	2	0
Apathy	13	0
Listless	12	0
<b><i>Narcolepsy and associated conditions</i></b>		
Hypnagogic hallucination	1	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Dermatophagia	3	0
<b><i>Orgasmic disorders and disturbances</i></b>		
Orgasm abnormal	1	0
Orgasmic sensation decreased	1	0
<b><i>Panic attacks and disorders</i></b>		
Limited symptom panic attack	1	0
Panic attack	58	0
Panic reaction	12	0
<b><i>Paraphilias and paraphilic disorders</i></b>		
Exhibitionism	1	0
<b><i>Parasomnias</i></b>		
Abnormal dreams	42	0
Abnormal sleep-related event	1	0
Nightmare	68	0
Sleep inertia	1	0
Sleep talking	3	0
Sleep terror	5	0
Somnambulism	1	0
<b><i>Perception disturbances NEC</i></b>		
Autoscopy	3	0
Deja vu	1	0
Derealisation	3	0
Illusion	1	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	14	0
<b><i>Psychiatric symptoms NEC</i></b>		
Helplessness	1	0
Hypervigilance	2	0
Psychiatric symptom	6	0
Psychological trauma	1	0
<b><i>Psychotic disorder NEC</i></b>		
Acute psychosis	1	0
Psychotic disorder	2	0
<b><i>Sexual arousal disorders</i></b>		
Disturbance in sexual arousal	1	0
<b><i>Sexual desire disorders</i></b>		
Libido decreased	6	0
Libido increased	1	0
Loss of libido	6	0
<b><i>Sexual dysfunction NEC</i></b>		
Genito-pelvic pain/penetration disorder	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	82	0
<b><i>Somatic symptom disorders</i></b>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> Psychiatric disorders cont'd		
Conversion disorder	5	0
Habit cough	7	0
<b><i>Speech and language usage disturbances</i></b>		
Disorganised speech	2	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	4	0
Lack of spontaneous speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	4	0
Head banging	7	0
<b><i>Stress disorders</i></b>		
Acute stress disorder	1	0
Post-traumatic stress disorder	1	0
<b><i>Substance related and addictive disorders</i></b>		
Alcoholism	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Intentional self-injury	2	0
Suicidal behaviour	2	0
Suicidal ideation	20	0
Suicide attempt	3	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	4	0
Intrusive thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	5	0
Thought blocking	2	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>2637</b>	<b>0</b>

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder irritation	2	0
Bladder pain	11	0
Dysuria	11	0
Incontinence	17	0
Micturition urgency	16	0
Pollakiuria	46	0
Stress urinary incontinence	1	0
Urethral pain	2	0
Urinary incontinence	19	0
Urinary retention	10	0
Urinary straining	2	0
Urine flow decreased	2	0
<i><b>Bladder disorders NEC</b></i>		
Bladder dilatation	1	0
Bladder disorder	4	0
Urinary bladder haemorrhage	2	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	1	0
<i><b>Genitourinary tract infections and inflammations NEC</b></i>		
Urinary tract inflammation	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis acute	1	0
IgA nephropathy	2	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	1	0
Hypertonic bladder	4	0
Loss of bladder sensation	2	0
<i><b>Nephritis NEC</b></i>		
Nephritis	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	2	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	7	0
Chronic kidney disease	2	0
Oliguria	1	0
Renal failure	2	0
Renal impairment	3	0
Renal injury	1	0
<i><b>Renal lithiasis</b></i>		
Nephrolithiasis	1	0
<i><b>Renal vascular and ischaemic conditions</b></i>		
Renal vein thrombosis	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	22	0
Haematuria	10	0
Loin pain haematuria syndrome	1	0
Urine abnormality	5	0
Urine odour abnormal	4	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	9	0
Nocturia	1	0
Polyuria	1	0



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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b> Renal & urinary disorders cont'd		
Renal pain	114	0
Urinary tract pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>347</b>	<b>0</b>

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	6	0
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	4	0
Breast mass	21	0
Fibrocystic breast disease	1	0
Retracted nipple	1	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	4	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	3	0
Breast discomfort	2	0
Breast haemorrhage	1	0
Breast oedema	1	0
Breast pain	158	0
Breast swelling	23	0
Breast tenderness	16	0
Nipple pain	2	0
Nipple swelling	2	0
<i><b>Cervix disorders NEC</b></i>		
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation delayed	1	0
Ejaculation failure	3	0
Erectile dysfunction	15	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><b>Gender disorders</b></i>		
Feminisation acquired	1	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	2	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	10	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	10	0
Premature menopause	5	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	24	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	486	0
Intermenstrual bleeding	255	0
Menstrual discomfort	4	0
Menstrual disorder	422	0
Menstruation irregular	695	0
Premenstrual dysphoric disorder	1	0
Premenstrual headache	2	0

## Case Series Drug Analysis Print

### Name: COVID-19 Moderna Vaccine Analysis Print

Report Run Date: 16-Jun-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b> Reproductive & breast disorders cont'd		
Premenstrual pain	23	0
Premenstrual syndrome	19	0
Withdrawal bleed	2	0
<b><i>Menstruation with decreased bleeding</i></b>		
Amenorrhoea	104	0
Hypomenorrhoea	117	0
Menstruation delayed	853	0
Oligomenorrhoea	35	0
<b><i>Menstruation with increased bleeding</i></b>		
Heavy menstrual bleeding	1076	0
Menometrorrhagia	9	0
Polymenorrhoea	182	0
<b><i>Ovarian and fallopian tube cysts and neoplasms</i></b>		
Ovarian cyst	7	0
Polycystic ovaries	11	0
<b><i>Ovarian and fallopian tube disorders NEC</i></b>		
Fallopian tube spasm	1	0
Ovulation pain	21	0
Premature ovulation	1	0
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Adnexa uteri pain	22	0
Pelvic haemorrhage	2	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Penile pain	1	0
Penis disorder	3	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	2	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatic pain	2	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Genital blister	1	0
Genital haemorrhage	3	0
Genital paraesthesia	1	0
Genital ulceration	3	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
Genital odour	1	0
Genital pain	4	0
Genital rash	1	0
Pelvic discomfort	1	0
Pelvic pain	37	0
<b><i>Scrotal disorders NEC</i></b>		
Scrotal pain	8	0
Scrotal swelling	1	0
Varicocele	2	0
<b><i>Sexual function and fertility disorders NEC</i></b>		
Infertility	5	0
Infertility female	1	0
Sexual dysfunction	2	0
<b><i>Spermatogenesis and semen disorders</i></b>		
Haematospermia	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular disorder	2	0
Testicular mass	1	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b> Reproductive & breast disorders cont'd		
Testicular pain	21	0
Testicular swelling	7	0
<b><i>Uterine disorders NEC</i></b>		
Adenomyosis	1	0
Endometrial hyperplasia	1	0
Endometriosis	22	0
Metrorrhoea	1	0
Uterine haemorrhage	12	0
Uterine pain	8	0
<b><i>Uterine neoplasms</i></b>		
Uterine polyp	1	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	17	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Vaginal cyst	1	0
Vulva cyst	1	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	349	0
Vaginal ulceration	3	0
Vulval haemorrhage	10	0
Vulval ulceration	4	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Coital bleeding	1	0
Labia enlarged	1	0
Vaginal discharge	21	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
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>5267</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Agonal respiration	1	0
Apnoea	1	0
Dyspnoea	1706	0
Dyspnoea at rest	1	0
Dyspnoea exertional	7	0
Hyperventilation	16	0
Hypopnoea	36	0
Hypoventilation	1	0
Irregular breathing	6	0
Mouth breathing	1	0
Obstructive sleep apnoea syndrome	2	0
Respiration abnormal	23	0
Respiratory arrest	2	1
Respiratory distress	2	0
Sleep apnoea syndrome	5	0
Tachypnoea	7	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	84	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	137	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Hypoxia	2	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	3	0
Cough	661	0
Haemoptysis	5	0
Productive cough	39	0
Sputum discoloured	6	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Hypersensitivity pneumonitis	2	0
Pneumonitis	5	0
Pulmonary sarcoidosis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	16	0
Lower respiratory tract congestion	2	0
Pleuritic pain	3	0
Pulmonary haemorrhage	1	0
Pulmonary pain	31	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	75	0
Nasal inflammation	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Rhinitis allergic	1	0
<b>Nasal disorders NEC</b>		
Epistaxis	208	0
Nasal crusting	1	0
Nasal dryness	3	0
Nasal oedema	2	0
Nasal pruritus	3	0
<b>Paranasal sinus disorders (excl infections and neoplasms)</b>		
Sinonasal obstruction	5	0
Sinus congestion	13	0
Sinus disorder	4	0
<b>Parenchymal lung disorders NEC</b>		
Interstitial lung disease	2	0
<b>Pharyngeal disorders (excl infections and neoplasms)</b>		
Pharyngeal erythema	3	0
Pharyngeal hypoaesthesia	5	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	5	0
Pharyngeal swelling	66	0
Tonsillar erythema	3	0
Tonsillar hypertrophy	17	0
Tonsillar inflammation	1	0
<b>Pleural infections and inflammations</b>		
Pleurisy	11	0
<b>Pneumothorax and pleural effusions NEC</b>		
Pleural effusion	4	0
<b>Pulmonary hypertensions</b>		
Pulmonary hypertension	1	0
<b>Pulmonary oedemas</b>		
Acute pulmonary oedema	1	0
Pulmonary congestion	2	0
Pulmonary oedema	6	0
<b>Pulmonary thrombotic and embolic conditions</b>		
Pulmonary embolism	76	3
Pulmonary thrombosis	3	0
<b>Respiratory failures (excl neonatal)</b>		
Respiratory failure	2	0
<b>Respiratory signs and symptoms NEC</b>		
Diaphragmalgia	4	0
Painful respiration	4	0
Respiratory symptom	4	0
Use of accessory respiratory muscles	2	0
<b>Respiratory tract disorders NEC</b>		
Allergic respiratory disease	2	0
Lung disorder	1	0
Pulmonary mass	1	0
Respiratory disorder	2	0
Respiratory tract congestion	1	0
Respiratory tract irritation	1	0
<b>Upper respiratory tract signs and symptoms</b>		
Aphonia	23	0
Catarrh	8	0
Choking	8	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Dry throat	32	0
Dysphonia	25	0
Increased viscosity of upper respiratory secretion	5	0
Nasal discomfort	9	0
Oropharyngeal blistering	2	0
Oropharyngeal discomfort	4	0
Oropharyngeal pain	614	0
Paranasal sinus discomfort	8	0
Rhinalgia	6	0
Rhinorrhoea	179	0
Sinus pain	77	0
Sneezing	61	0
Throat irritation	44	0
Throat tightness	56	0
Upper-airway cough syndrome	5	0
Yawning	9	0
<b>Respiratory disorders SOC TOTAL</b>	<b>4552</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	38	0
Acne cystic	2	0
Dermatitis acneiform	1	0
<b><i>Alopecias</i></b>		
Alopecia	75	0
Alopecia areata	18	0
Alopecia totalis	2	0
<b><i>Angioedemas</i></b>		
Angioedema	69	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	294	0
Hidradenitis	2	0
Hyperhidrosis	1034	0
Miliaria	71	0
Night sweats	323	0
<b><i>Bullous conditions</i></b>		
Blister	105	0
Blister rupture	2	0
Blood blister	3	0
Dermatitis bullous	5	0
Erythema multiforme	16	0
Pemphigoid	2	0
Pemphigus	1	0
Stevens-Johnson syndrome	1	0
<b><i>Connective tissue disorders</i></b>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	108	0
Pain of skin	149	0
Papule	22	0
Scab	5	0
Scar pain	6	0
Sensitive skin	152	0
Skin burning sensation	80	0
Skin discolouration	47	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	124	0
Skin sensitisation	16	0
Skin swelling	32	0
Skin texture abnormal	1	0
Skin tightness	7	0
Skin warm	239	0
Skin weeping	4	0
Yellow skin	5	0



# Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Dermatitis and eczema</i></b>		
Autoimmune dermatitis	1	0
Dermatitis	50	0
Dermatitis allergic	117	0
Dermatitis atopic	19	0
Dermatitis contact	10	0
Dyshidrotic eczema	12	0
Eczema	94	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	2	0
Flagellate dermatitis	1	0
Hand dermatitis	1	0
Neurodermatitis	1	0
Skin irritation	42	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	5	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	1239	0
Vancomycin infusion reaction	1	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative generalised	2	1
Exfoliative rash	4	0
Skin exfoliation	23	0
<b><i>Hyperpigmentation disorders</i></b>		
Ephelides	2	0
Skin hyperpigmentation	1	0
Solar lentigo	1	0
<b><i>Hypopigmentation disorders</i></b>		
Skin hypopigmentation	2	0
Vitiligo	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	1	0
Nail ridging	1	0
Onychalgia	1	0
Onychoclasia	2	0
Onychomadesis	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	11	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	5	0
Parapsoriasis	1	0
Pityriasis rosea	21	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	20	0
<b><i>Pigmentation changes NEC</i></b>		
Pigmentation disorder	2	0
<b><i>Pilar disorders NEC</i></b>		
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	17	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Trichodynia	1	0
Trichorrhexis	1	0
<b>Pruritus NEC</b>		
Itching scar	4	0
Pruritus	2602	0
<b>Psoriatic conditions</b>		
Guttate psoriasis	2	0
Palmoplantar pustulosis	1	0
Psoriasis	40	0
Rebound psoriasis	1	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	1	0
Petechiae	26	0
Purpura	13	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	1	0
Rash	2991	0
Rash erythematous	1135	0
Rash macular	207	0
Rash maculo-papular	8	0
Rash morbilliform	9	0
Rash papular	190	0
Rash pruritic	641	0
Rash vesicular	14	0
<b>Rosaceas</b>		
Rosacea	2	0
<b>Scaly conditions</b>		
Pityriasis	6	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	2	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	4	0
Skin mass	13	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Skin erosion	8	0
Skin ulcer	6	0
<b>Skin cysts and polyps</b>		
Dermal cyst	8	0
<b>Skin dystrophies</b>		
Keloid scar	2	0
Skin wrinkling	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	4	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	3	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	1	0
Needle track marks	2	0
<b>Skin vasculitides</b>		
Capillaritis	1	0
Cutaneous vasculitis	3	0
Hypersensitivity vasculitis	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Vasculitic rash	3	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	5	0
<b>Telangiectasia and related conditions</b>		
Spider naevus	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	5	0
Cold urticaria	1	0
Idiopathic urticaria	5	0
Mechanical urticaria	27	0
Urticaria	725	0
Urticaria aquagenic	1	0
Urticaria cholinergic	1	0
Urticaria chronic	8	0
Urticaria contact	1	0
Urticaria papular	1	0
Urticularial vasculitis	1	0
<b>Skin disorders SOC TOTAL</b>	<b>13572</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Menarche	2	0
Menopause	10	0
Postmenopause	2	0
<i><b>Disability issues</b></i>		
Bedridden	11	0
Disability	1	0
Immobile	7	0
Impaired driving ability	2	0
Impaired work ability	3	0
Loss of personal independence in daily activities	14	0
Sight disability	2	0
Walking aid user	1	0
<i><b>Employment issues</b></i>		
Retirement	2	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	6	0
<i><b>Social issues NEC</b></i>		
Social problem	1	0
Tattoo	1	0
<b>Social circumstances SOC TOTAL</b>	<b>67</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i><b>Anaesthesia and allied procedures</b></i>		
Light anaesthesia	1	0
<i><b>Analgesia supportive care</b></i>		
Analgesic therapy	1	0
<i><b>Breast therapeutic procedures NEC</b></i>		
Axillary lymphadenectomy	2	0
<i><b>Contraceptive methods female</b></i>		
Post coital contraception	1	0
<i><b>Dental and gingival therapeutic procedures</b></i>		
Tooth extraction	1	0
<i><b>Dietary and nutritional therapies</b></i>		
Medical diet	1	0
<i><b>Eye therapeutic procedures NEC</b></i>		
Eye irrigation	1	0
<i><b>Gastrointestinal therapeutic procedures NEC</b></i>		
Prophylaxis of nausea and vomiting	2	0
<i><b>Gynaecological therapeutic procedures NEC</b></i>		
Menstrual cycle management	3	0
<i><b>Hormonal therapeutic procedures NEC</b></i>		
Hormone replacement therapy	1	0
<i><b>Immunisations</b></i>		
COVID-19 immunisation	23	0
Immunisation	22	0
Influenza immunisation	1	0
Vaccine coadministration	1	0
<i><b>Joint therapeutic procedures</b></i>		
Joint injection	1	0
Joint stabilisation	1	0
<i><b>Limb therapeutic procedures</b></i>		
Limb immobilisation	1	0
<i><b>Psychiatric therapies</b></i>		
Electroconvulsive therapy	1	0
<i><b>Respiratory tract therapeutic procedures NEC</b></i>		
Asthma prophylaxis	2	0
<i><b>Skin and subcutaneous tissue therapeutic procedures NEC</b></i>		
Dermal filler injection	3	0
<i><b>Therapeutic procedures NEC</b></i>		
Bed rest	4	0
Botulinum toxin injection	1	0
Hospitalisation	4	0
Injection	17	0
Interchange of vaccine products	45	0
Polypectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>142</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive urgency	1	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Aneurysm ruptured	1	0
<b><i>Aortic necrosis and vascular insufficiency</i></b>		
Aortic stenosis	1	0
<b><i>Arterial infections and inflammations</i></b>		
Giant cell arteritis	5	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	3	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	9	0
Neurogenic shock	1	0
Shock	6	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	2	0
Haematoma	9	0
Haemorrhage	241	0
Internal haemorrhage	3	0
<b><i>Lymphangiopathies</i></b>		
Lymphocele	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	29	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Embolism	3	0
Embolism venous	1	0
Thrombosis	72	0
Venous thrombosis	1	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arterial spasm	1	0
Arteriosclerosis	1	0
Infarction	1	0
Ischaemia	1	0
Peripheral venous disease	1	0
Vasospasm	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Vascular pain	8	0
Vasodilatation	3	0
Vein discolouration	1	0
Vein rupture	2	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Axillary vein thrombosis	1	0
Blue toe syndrome	8	0
Deep vein thrombosis	63	0
Pelvic venous thrombosis	2	0
Superficial vein thrombosis	3	0
Thrombophlebitis	6	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	14	0
Erythromelalgia	1	0
Flushing	59	0
Hot flush	320	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Extremity necrosis	1	0
Peripheral coldness	112	0
Peripheral ischaemia	1	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	11	0
<b><i>Phlebitis NEC</i></b>		
Phlebitis	1	0
Phlebitis superficial	1	0
<b><i>Site specific vascular disorders NEC</i></b>		
Pallor	90	0
<b><i>Varicose veins NEC</i></b>		
Spider vein	1	0
Varicophlebitis	1	0
Varicose vein	8	0
Varicose vein ruptured	1	0
<b><i>Vascular hypertensive disorders NEC</i></b>		
Hypertension	129	0
Prehypertension	1	0
White coat hypertension	1	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	2	0
Hypotension	119	0
Orthostatic hypotension	6	0
<b><i>Vasculitides NEC</i></b>		
MAGIC syndrome	1	0
Vasculitis	9	0
<b><i>Vena caval embolism and thrombosis</i></b>		
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1385</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>130851</b>	<b>62</b>
<b>TOTAL REPORTS</b>	<b>39514</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>62</b>