

COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021
Data Lock Date: 23-Jun-2021 18:30:09

All UK spontaneous reports received between 04/01/21 and 23/06/21 for COVID-19 vaccine Oxford University/AstraZeneca.

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

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	11	0
Iron deficiency anaemia	9	0
Pernicious anaemia	3	0
<i>Anaemias NEC</i>		
Anaemia	110	0
Blood loss anaemia	3	0
Hypochromic anaemia	1	0
Microcytic anaemia	1	0
Normocytic anaemia	2	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	9	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	4	0
Warm type haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Atypical haemolytic uraemic syndrome	1	0
Red cell fragmentation syndrome	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	107	0
Spontaneous haematoma	8	0
Spontaneous haemorrhage	1	0
<i>Coagulation factor deficiencies</i>		
Hypofibrinogenaemia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	9	0
Antiphospholipid syndrome	23	0
Coagulopathy	55	0
Disseminated intravascular coagulation	17	2
Hypercoagulation	22	1
<i>Eosinophilic disorders</i>		
Eosinophilia	18	0
Hypereosinophilic syndrome	1	0
<i>Haematological cysts and polyps</i>		
Splenic cyst	1	0
<i>Haematological disorders</i>		
Blood disorder	9	0
Bone marrow disorder	2	0
Bone marrow oedema	1	0
Mast cell activation syndrome	5	0
Mastocytosis	2	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	8	0
<i>Leukocytoses NEC</i>		
Leukocytosis	3	0
Lymphocytosis	8	0
Monocytosis	2	0
Neutrophilia	14	0
<i>Leukopenias NEC</i>		
Leukopenia	9	0
Lymphopenia	9	0
<i>Lymphatic system disorders NEC</i>		

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Blood disorders Blood disorders cont'd		
Abdominal lymphadenopathy	1	0
Lymph node fibrosis	1	0
Lymph node pain	529	0
Lymphadenitis	28	0
Lymphadenopathy	4553	0
Lymphatic disorder	1	0
Pseudolymphoma	3	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	2	0
Myelosuppression	4	0
Pancytopenia	18	0
<i>Neutropenias</i>		
Agranulocytosis	4	0
Autoimmune neutropenia	1	0
Febrile neutropenia	1	0
Neutropenia	75	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	3	0
Platelet disorder	7	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	2	0
Stress polycythaemia	3	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	4	0
<i>Red blood cell abnormal findings NEC</i>		
Anisocytosis	2	0
Macrocytosis	2	0
Poikilocytosis	1	0
Polychromasia	3	0
Rouleaux formation	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	5	0
<i>Spleen disorders</i>		
Spleen disorder	1	0
Splenic artery thrombosis	2	0
Splenic haemorrhage	1	0
Splenic infarction	12	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	9	0
Splenomegaly	4	0
<i>Thrombocytopenias</i>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	11	0
Immune thrombocytopenia	200	1
Thrombocytopenia	800	5
Thrombocytopenic purpura	9	0
Thrombotic thrombocytopenic purpura	4	0
<i>Thrombocytoses</i>		
Thrombocytosis	11	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	6819	9

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	21	0
Atrioventricular block complete	3	0
Atrioventricular block first degree	1	0
Atrioventricular block second degree	4	0
Brugada syndrome	1	0
Bundle branch block	1	0
Bundle branch block left	6	0
Bundle branch block right	4	0
Long QT syndrome	1	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	4	2
Atrial thrombosis	4	0
Cardiac disorder	61	1
Cardiac dysfunction	1	0
Cardiac ventricular thrombosis	9	2
Cardiovascular disorder	8	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	8	1
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	13	0
Cardiovascular symptom	2	0
Palpitations	4646	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	9	1
Congestive cardiomyopathy	8	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	2	1
Coronary artery disease	7	0
Coronary artery dissection	1	0
Coronary artery embolism	1	0
Coronary artery occlusion	1	0
Coronary artery thrombosis	12	3
<i>Heart failures NEC</i>		
Cardiac failure	60	9
Cardiac failure acute	6	0
Cardiac failure chronic	1	1
Cardiac failure congestive	2	1
Cardiogenic shock	7	2
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		

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Cardiac disorders Cardiac disorders cont'd		
Acute coronary syndrome	7	0
Acute myocardial infarction	60	9
Angina pectoris	179	0
Angina unstable	14	0
Arteriospasm coronary	5	0
Microvascular coronary artery disease	2	0
Myocardial infarction	323	43
Myocardial ischaemia	21	9
Prinzmetal angina	1	0
Left ventricular failures		
Acute left ventricular failure	1	0
Left ventricular failure	3	1
Mitral valvular disorders		
Mitral valve incompetence	6	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiomegaly	14	0
Diastolic dysfunction	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	15	0
Left ventricular hypertrophy	1	0
Myocardial rupture	1	0
Right atrial dilatation	2	0
Right ventricular dilatation	2	0
Right ventricular dysfunction	4	0
Systolic dysfunction	1	0
Ventricular hypertrophy	4	1
Noninfectious myocarditis		
Myocarditis	51	1
Noninfectious pericarditis		
Pericarditis	89	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	21	0
Pericardial haemorrhage	5	2
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	113	2
Arrhythmia neonatal	1	0
Bradycardia	73	0
Cardiac fibrillation	6	0
Cardiac flutter	199	0
Extrasystoles	121	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	13	0
Tachyarrhythmia	11	0
Tachycardia	1183	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	3	1
Supraventricular arrhythmias		

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Cardiac disorders Cardiac disorders cont'd		
Arrhythmia supraventricular	13	0
Atrial fibrillation	271	0
Atrial flutter	28	0
Atrial tachycardia	3	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	3	0
Sinus node dysfunction	1	0
Sinus tachycardia	64	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	33	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	5	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	146	32
Cardio-respiratory arrest	2	1
Pulseless electrical activity	5	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	7	0
Ventricular fibrillation	6	0
Ventricular tachycardia	13	0
Cardiac disorders SOC TOTAL	8108	130

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	7	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	3	0
Ventricular septal defect	1	0
<i>Central nervous system disorders congenital NEC</i>		
Encephalocele	1	0
Neural tube defect	1	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	0
Congenital hydrocephalus	1	0
<i>Coagulation disorders congenital</i>		
Factor VII deficiency	1	0
Protein C deficiency	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	1	0
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Great vessel disorders congenital</i>		
Coarctation of the aorta	1	0
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Neonatal alloimmune thrombocytopenia	3	0
<i>Haemoglobinopathies congenital</i>		
Sickle cell trait	1	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria acute	1	0
<i>Lacrimal system disorders congenital</i>		
Dacryostenosis congenital	1	0
<i>Lysosomal storage disorders</i>		
Mucopolysaccharidosis	1	0
<i>Male reproductive tract disorders congenital</i>		
Hydrocele	2	0
Micropenis	2	0
Penoscrotal fusion	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Limb reduction defect	2	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	2	0
<i>Neurological disorders congenital NEC</i>		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	1	0
<i>Non-site specific muscle disorders congenital</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Rippling muscle disease	1	0
Ocular disorders congenital NEC		
Colour blindness	2	0
Pancreatic disorders congenital		
Hereditary pancreatitis	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	13	0
Pulmonary and bronchial disorders congenital		
Cystic fibrosis	2	0
Sex chromosomal abnormalities		
Klinefelter's syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Macroglossia	1	0
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	72	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	29	0
Ear discomfort	96	0
Ear disorder	14	0
Ear haemorrhage	13	0
Ear pain	1882	0
Ear pruritus	5	0
Ear swelling	70	0
Otorrhoea	6	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	1	0
Eustachian tube obstruction	6	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	30	0
External ear pain	11	0
Juvenile spring eruption	1	0
Red ear syndrome	5	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	8	0
<i>Hearing losses</i>		
Deafness	310	0
Deafness bilateral	15	0
Deafness neurosensory	28	0
Deafness transitory	3	0
Deafness unilateral	46	0
Hypoacusis	189	0
Mixed deafness	1	0
Neurosensory hypoacusis	1	0
Sudden hearing loss	57	0
<i>Hyperacusia</i>		
Hyperacusis	132	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	5	0
Meniere's disease	24	0
Vestibular disorder	8	0
<i>Inner ear infections and inflammations</i>		
Autoimmune inner ear disease	1	0
Inner ear inflammation	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	107	0
Phobic postural vertigo	2	0
Tinnitus	3449	0
Vertigo	1862	0
Vertigo labyrinthine	12	0
Vertigo positional	121	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	1	0
Middle ear effusion	4	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	4	0
Ear disorders SOC TOTAL	8571	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	6	0
Thyroiditis	11	0
Thyroiditis acute	4	0
Thyroiditis chronic	1	0
Thyroiditis subacute	1	0
<i>Adrenal cortical hyperfunctions</i>		
Cushing's syndrome	1	0
Cushingoid	5	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	15	0
Adrenocortical insufficiency acute	29	0
Glucocorticoid deficiency	1	0
Secondary adrenocortical insufficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
Adrenal haemorrhage	7	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
Adrenomegaly	1	0
Haemorrhagic adrenal infarction	4	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	2	0
<i>Ectopic endocrine disorders</i>		
Carcinoid syndrome	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
Premature menarche	11	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	13	0
Ovulation delayed	10	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	2	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	2	0
Primary hypoparathyroidism	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	2	0
Pituitary apoplexy	1	0
Pituitary haemorrhage	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	7	0
Inappropriate antidiuretic hormone secretion	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Euthyroid sick syndrome	1	0
Goitre	15	0
Thyroid disorder	14	0
Thyroid mass	5	0
Thyroid pain	12	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	5	0

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Reaction Name	Total	Fatal
Endocrine disorders Endocrine disorders cont'd		
Hyperthyroidism	33	0
Thyrotoxic crisis	3	0
Thyroid hypofunction disorders		
Hypothyroidism	46	0
Thyroid neoplasms		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	283	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	10	0
<i>Cataract conditions</i>		
Cataract	14	0
Cataract cortical	2	0
Cataract subcapsular	4	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Vitreous haemorrhage	5	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	2	0
Vitreous detachment	43	0
Vitreous floaters	152	0
Vitreous opacities	1	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	18	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	117	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	2	0
Ulcerative keratitis	2	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal perforation	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	120	0
Excessive eye blinking	7	0
Eyelid myokymia	1	0
Eyelid ptosis	45	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	4	0
Glaucoma	8	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	9	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	21	0
Iritis	12	0
Uveitis	38	0
<i>Lacrimation disorders</i>		
Dry eye	268	0
Lacrimation increased	229	0
<i>Lens structural change, deposit and degeneration (excl cataracts)</i>		
Anterior capsule contraction	1	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	3	0
Eyelid haematoma	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	20	0
Chalazion	2	0
Eczema eyelids	3	0
Erythema of eyelid	6	0

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Eye disorders Eye disorders cont'd		
Eyelid cyst	16	0
Eyelid irritation	4	0
Eyelid margin crusting	1	0
Eyelid oedema	12	0
Eyelid rash	12	0
Meibomianitis	1	0
Swelling of eyelid	115	0
Lid, lash and lacrimal structural disorders		
Eyelid exfoliation	3	0
Eyelid skin dryness	4	0
Eyelid thickening	4	0
Growth of eyelashes	7	0
Lagophthalmos	3	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	3	0
Eye haemorrhage	92	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	3	0
Ocular cysts and polyps		
Vitreous cyst	1	0
Ocular disorders NEC		
Dark circles under eyes	8	0
Eye disorder	25	0
Eye oedema	15	0
Eye pain	3138	0
Eye swelling	559	0
Eye symptom	10	0
Eye ulcer	9	0
Eyelid disorder	11	0
Eyelid pain	19	0
Eyelids pruritus	9	0
Ocular discomfort	65	0
Periorbital discomfort	1	0
Periorbital oedema	16	0
Periorbital pain	3	0
Periorbital swelling	92	0
Retinal disorder	1	0
Ocular infections, inflammations and associated manifestations		
Autoimmune eye disorder	1	0
Eye allergy	27	0
Eye discharge	23	0
Eye inflammation	29	0
Eye irritation	191	0
Eye pruritus	278	0
Limbal swelling	7	0
Ocular hyperaemia	403	0
Ocular rosacea	1	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	10	0
Eye movement disorder	43	0
Gaze palsy	3	0
Ocular myasthenia	2	0
Ophthalmoplegia	1	0

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Eye disorders Eye disorders cont'd		
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	24	0
Asthenopia	331	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	35	0
Hypoaesthesia eye	27	0
Photophobia	953	0
Optic disc abnormalities NEC		
Optic atrophy	1	0
Optic discs blurred	2	0
Papilloedema	12	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	2	0
Optic ischaemic neuropathy	10	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	3	0
Pupil disorders		
Miosis	14	0
Mydriasis	30	0
Pupil fixed	11	0
Pupillary deformity	1	0
Pupils unequal	10	0
Refractive and accommodative disorders		
Altered visual depth perception	5	0
Hypermetropia	1	0
Myopia	3	0
Refraction disorder	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	2	0
Retinal artery embolism	3	0
Retinal artery occlusion	20	0
Retinal haemorrhage	16	0
Retinal infarction	1	0
Retinal vascular occlusion	2	0
Retinal vascular thrombosis	3	0
Retinal vein occlusion	68	0
Retinal vein thrombosis	6	0
Retinal vein varices	1	0
Retinal structural change, deposit and degeneration		
Macular cyst	1	0
Macular degeneration	7	0
Macular detachment	1	0
Macular hole	2	0
Neovascular age-related macular degeneration	10	0
Retinal detachment	22	0
Retinal drusen	1	0
Retinal tear	12	0
Retinal toxicity	5	0
Vitreoretinal traction syndrome	1	0
Retinal, choroid and vitreous infections and inflammations		
Macular oedema	5	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal oedema	1	0
Retinopathies NEC		
Acute macular outer retinopathy	4	0
Acute zonal occult outer retinopathy	1	0
Diabetic retinopathy	2	0
Retinal exudates	15	0
Retinopathy	7	0
Scleral infections, irritations and inflammations		
Episcleritis	14	0
Scleritis	8	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	1	0
Structural change, deposit and degeneration of eye NEC		
Deposit eye	1	0
Endocrine ophthalmopathy	3	0
Exophthalmos	5	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	2	0
Erythropsia	5	0
Xanthopsia	9	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Diplopia	287	0
Dysmetropsia	1	0
Halo vision	12	0
Metamorphopsia	35	0
Oscillopsia	1	0
Photopsia	299	0
Scintillating scotoma	7	0
Vision blurred	2582	0
Visual brightness	9	0
Visual snow syndrome	4	0
Visual field disorders		
Visual field defect	26	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	8	0
Blindness	247	0
Blindness day	1	0
Blindness transient	22	0
Blindness unilateral	32	0
Central vision loss	2	0
Night blindness	4	0
Sudden visual loss	5	0
Visual acuity reduced	32	0
Visual acuity reduced transiently	1	0
Visual impairment	634	0
Visual pathway disorders		
Optic nerve disorder	2	0
Optic neuropathy	7	0
Eye disorders SOC TOTAL	12481	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	4	0
Gastrointestinal sounds abnormal	21	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	32	1
Pancreatitis acute	16	0
Pancreatitis chronic	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
<i>Anal and rectal pains</i>		
Proctalgia	25	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	2	0
Anal hypoaesthesia	4	0
Anal inflammation	1	0
Anal paraesthesia	2	0
Anal pruritus	5	0
Anal spasm	1	0
Anorectal discomfort	7	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal spasm	1	0
Rectal tenesmus	2	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	12	0
Tongue cyst	5	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	44	0
Colitis ischaemic	5	1
Colitis microscopic	6	0
Colitis ulcerative	82	0
Crohn's disease	79	0
Inflammatory bowel disease	10	0
Terminal ileitis	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	4	0
<i>Dental disorders NEC</i>		
Diastema	1	0
Loose tooth	2	0
Malpositioned teeth	1	0
Teething	20	0
Tooth disorder	2	0
Tooth socket haemorrhage	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	12	0
Dental paraesthesia	17	0
Hyperaesthesia teeth	52	0
Hypoaesthesia teeth	2	0
Toothache	304	0
<i>Dental pulp disorders</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dental pulp disorder	1	0
Dental surface disorders		
Tooth discolouration	17	0
Diaphragmatic hernias		
Hiatus hernia	12	0
Diarrhoea (excl infective)		
Diarrhoea	8337	0
Diarrhoea haemorrhagic	30	0
Diverticula		
Diverticulum	10	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	1	0
Superior mesenteric artery syndrome	1	0
Duodenal ulcers and perforation		
Duodenal ulcer	2	0
Duodenal ulcer haemorrhage	2	1
Dyspeptic signs and symptoms		
Dyspepsia	804	0
Epigastric discomfort	18	0
Eructation	92	0
Faecal abnormalities NEC		
Abnormal faeces	20	0
Faecaloma	3	0
Faeces discoloured	47	0
Faeces hard	4	0
Faeces pale	6	0
Faeces soft	20	0
Mucous stools	14	0
Flatulence, bloating and distension		
Abdominal distension	534	0
Flatulence	371	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	9	0
Gastric ulcers and perforation		
Gastric ulcer	12	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
Gastritis (excl infective)		
Chronic gastritis	3	0
Gastritis	84	0
Reflux gastritis	14	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	3	0
Abdominal pain	4217	0
Abdominal pain lower	224	0
Abdominal pain upper	4855	0
Abdominal rigidity	50	0
Abdominal tenderness	19	0
Gastrointestinal pain	296	0
Oesophageal pain	6	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	424	0
Duodenogastric reflux	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastric dilatation	18	0
Gastrooesophageal reflux disease	201	0
Impaired gastric emptying	5	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Gastrointestinal disorders NEC		
Appendix disorder	1	0
Food poisoning	12	0
Functional gastrointestinal disorder	10	0
Gastric disorder	10	0
Gastrointestinal disorder	31	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	1	0
Stomach mass	1	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	4	0
Change of bowel habit	16	0
Defaecation disorder	1	0
Dyschezia	13	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	2	0
Gastrointestinal fistulae		
Anal fistula	1	0
Gastrointestinal inflammatory disorders NEC		
Appendicitis noninfective	2	0
Enteritis	1	0
Gastrointestinal inflammation	1	0
Gastrointestinal tract irritation	4	0
Intestinal angioedema	1	0
Ischaemic enteritis	1	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Achlorhydria	1	0
Hyperchlorhydria	3	0
Gastrointestinal necrosis and gangrene (excl gangrenous hernia)		
Gastrointestinal necrosis	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	1484	0
Abdominal symptom	5	0
Acute abdomen	16	0
Anal incontinence	40	0
Breath odour	23	0
Dysphagia	221	0
Intestinal congestion	1	0
Odynophagia	32	0
Gastrointestinal spastic and hypermotility disorders		
Cardiospasm	2	1
Defaecation urgency	15	0
Frequent bowel movements	44	0
Irritable bowel syndrome	120	0
Oesophageal spasm	6	0
Gastrointestinal stenosis and obstruction NEC		
Intestinal obstruction	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Intussusception	1	0
Volvulus	1	1
<i>Gastrointestinal ulcers and perforation, site unspecified</i>		
Diverticular perforation	2	0
Gastrointestinal perforation	1	0
Gastrointestinal ulcer	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	8	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal infarction	4	0
Intestinal ischaemia	28	1
Mesenteric artery embolism	1	0
Mesenteric artery thrombosis	3	0
Mesenteric vein thrombosis	16	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	3	0
Visceral venous thrombosis	11	1
<i>Gingival disorders, signs and symptoms NEC</i>		
Amalgam tattoo	1	0
Epulis	1	0
Gingival atrophy	1	0
Gingival blister	22	0
Gingival discomfort	5	0
Gingival disorder	12	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	216	0
Gingival pruritus	1	0
Gingival recession	2	0
Gingival swelling	47	0
Gingival ulceration	8	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	20	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	147	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoidal haemorrhage	4	0
Haemorrhoids	59	0
Haemorrhoids thrombosed	11	0
<i>Inguinal hernias</i>		
Inguinal hernia	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	35	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	4	0
Rectal haemorrhage	100	0
Small intestinal haemorrhage	27	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	4	0
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Large intestinal stenosis	1	0
Malabsorption syndromes		
Bile acid malabsorption	1	0
Coeliac disease	19	0
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Acetonaemic vomiting	1	0
Discoloured vomit	18	0
Faecal vomiting	3	0
Infantile vomiting	2	0
Nausea	31971	0
Regurgitation	3	0
Retching	222	0
Vomiting	10778	1
Vomiting projectile	150	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	29	0
Haematemesis	71	0
Haematochezia	90	0
Intra-abdominal haematoma	1	0
Melaena	8	0
Upper gastrointestinal haemorrhage	4	0
Oesophageal disorders NEC		
Oesophageal disorder	2	0
Oesophageal stenosis and obstruction		
Oesophageal obstruction	1	0
Oesophageal ulcers and perforation		
Oesophageal ulcer	1	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	3	0
Oesophagitis	15	0
Oral dryness and saliva altered		
Aptyalism	4	0
Dry mouth	1092	0
Lip dry	76	0
Saliva altered	6	0
Saliva discolouration	1	0
Salivary hypersecretion	76	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	4	0
Chapped lips	21	0
Cheilitis	34	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	34	0
Lip disorder	4	0
Oral disorder	15	0
Oral lichen planus	11	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
Oral soft tissue haemorrhages		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Lip haemorrhage	3	0
Mouth haemorrhage	44	0
Oral blood blister	49	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	9	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	8	0
Burning mouth syndrome	14	0
Coating in mouth	4	0
Hypoaesthesia oral	595	0
Lip discolouration	1	0
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	58	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	88	0
Oral mucosal blistering	30	0
Oral mucosal eruption	27	0
Oral mucosal erythema	4	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral pain	338	0
Oral pruritus	20	0
Paraesthesia oral	799	0
Oral soft tissue swelling and oedema		
Lip oedema	9	0
Lip swelling	896	0
Mouth swelling	116	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	13	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic mass	1	0
Pancreatic steatosis	1	0
Peptic ulcers and perforation		
Peptic ulcer	2	0
Peptic ulcer haemorrhage	4	0
Peritoneal and retroperitoneal disorders		
Ascites	6	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	0
Rectal inflammations NEC		
Proctitis	3	0
Salivary gland disorders NEC		
Salivary gland calculus	3	0
Salivary gland mass	2	0
Salivary gland pain	12	0
Salivary gland enlargements		
Parotid gland enlargement	12	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Salivary gland enlargement	5	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Aphthous ulcer	62	0
Lip ulceration	15	0
Mouth ulceration	702	0
Stomatitis	100	0
Tongue disorders		
Glossitis	16	0
Plicated tongue	4	0
Tongue disorder	29	0
Tongue geographic	3	0
Tongue haemorrhage	2	0
Tongue ulceration	31	0
Trichoglossia	6	0
Tongue signs and symptoms		
Glossodynia	244	0
Scalloped tongue	4	0
Stiff tongue	5	0
Strawberry tongue	1	0
Swollen tongue	569	0
Tongue blistering	27	0
Tongue coated	35	0
Tongue discolouration	34	0
Tongue discomfort	50	0
Tongue dry	20	0
Tongue eruption	10	0
Tongue erythema	6	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	16	0
Tongue pruritus	3	0
Tongue rough	2	0
Tongue spasm	3	0
Tooth missing		
Tooth loss	7	0
Gastrointestinal disorders SOC TOTAL	74587	9

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	16	0
Administration site coldness	1	0
Administration site erythema	6	0
Administration site extravasation	2	0
Administration site haemorrhage	1	0
Administration site induration	1	0
Administration site irritation	1	0
Administration site mass	1	0
Administration site pain	41	0
Administration site rash	3	0
Administration site reaction	5	0
Administration site swelling	4	0
Administration site urticaria	5	0
Administration site warmth	1	0
Puncture site bruise	59	0
Puncture site haemorrhage	1	0
Puncture site pain	22	0
Puncture site reaction	3	0
Puncture site swelling	1	0
Vessel puncture site bruise	1	0
<i>Adverse effect absent</i>		
No adverse event	14	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site bruise	24	0
Application site burn	4	0
Application site coldness	1	0
Application site discharge	1	0
Application site discolouration	1	0
Application site erythema	28	0
Application site exfoliation	1	0
Application site haemorrhage	1	0
Application site hypersensitivity	1	0
Application site hypoaesthesia	2	0
Application site inflammation	1	0
Application site joint pain	1	0
Application site odour	1	0
Application site pain	46	0
Application site pruritus	18	0
Application site rash	4	0
Application site reaction	1	0
Application site scar	1	0
Application site swelling	4	0
Application site vesicles	11	0
Application site warmth	2	0
Application site wound	1	0
Instillation site bruise	1	0
Instillation site discomfort	1	0
Instillation site pain	5	0
Instillation site pruritus	1	0
Instillation site warmth	12	0
<i>Asthenic conditions</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Asthenia	4490	3
Chronic fatigue syndrome	121	0
Decreased activity	9	0
Fatigue	46827	0
Malaise	11737	3
Sluggishness	24	0
Body temperature altered		
Hyperthermia	10	0
Hypothermia	51	0
Temperature regulation disorder	26	0
Complications associated with device NEC		
Complication of device removal	1	0
Injury associated with device	9	0
Medical device site joint pain	1	0
Phantom shocks	4	0
Death and sudden death		
Brain death	4	3
Death	280	280
Drowning	1	0
Sudden death	30	30
Sudden unexplained death in epilepsy	1	1
Febrile disorders		
Hyperpyrexia	40	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	53317	0
Feelings and sensations NEC		
Chills	42037	0
Early satiety	1	0
Feeling abnormal	2870	0
Feeling cold	5069	0
Feeling drunk	123	0
Feeling hot	2301	0
Feeling jittery	42	0
Feeling of body temperature change	922	0
Feeling of relaxation	1	0
Hangover	178	0
Hunger	77	0
Sensation of blood flow	14	0
Sensation of foreign body	47	0
Temperature intolerance	71	0
Thirst	1209	0
Thirst decreased	11	0
Fibrosis NEC		
Fibrosis	5	0
Gait disturbances		
Decreased gait velocity	3	0
Gait disturbance	372	0
Gait inability	181	0
Loss of control of legs	49	0
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Condition aggravated	227	0
Crepitations	7	0
Crying	262	0
Deformity	1	0
Developmental delay	6	0
Discharge	7	0
Disease progression	1	0
Disease recurrence	1	0
Effusion	1	0
Energy increased	26	0
Exercise tolerance decreased	30	0
Foaming at mouth	4	0
General physical health deterioration	20	1
General symptom	9	0
Glassy eyes	6	0
High-pitched crying	6	0
Ill-defined disorder	5	0
Illness	4746	0
Induration	21	0
Influenza like illness	9167	1
Irritability postvaccinal	3	0
Local reaction	155	0
Moaning	8	0
Multiple organ dysfunction syndrome	18	8
Nonspecific reaction	3	0
Organ failure	1	0
Perforation	2	0
Peripheral swelling	5379	0
Pre-existing condition improved	14	0
Premature ageing	1	0
Prolapse	1	0
Screaming	27	0
Secretion discharge	31	0
Sensitivity to weather change	1	0
Stenosis	1	0
Swelling	2516	0
Swelling face	964	0
Symptom recurrence	4	0
Tissue discolouration	1	0
Tissue infiltration	1	0
Unevaluable event	5	0
Healing abnormal NEC		
Impaired healing	3	0
Hernias NEC		
Hernia	4	0
Implant and catheter site reactions		
Catheter site urticaria	1	0
Implant site coldness	1	0
Implant site discharge	1	0
Implant site discolouration	4	0
Implant site hypoaesthesia	2	0
Implant site pain	4	0
Implant site rash	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site swelling	3	0
Implant site urticaria	1	0
Implant site vesicles	1	0
Implant site warmth	7	0
Inflammations		
Granuloma	1	0
Inflammation	669	0
Systemic inflammatory response syndrome	3	0
Infusion site reactions		
Infusion site bruising	1	0
Infusion site discomfort	1	0
Infusion site erythema	3	0
Infusion site joint pain	1	0
Infusion site mass	5	0
Infusion site nodule	2	0
Infusion site pain	12	0
Infusion site urticaria	2	0
Infusion site warmth	6	0
Injection site reactions		
Injected limb mobility decreased	39	0
Injection site atrophy	9	0
Injection site bruising	115	0
Injection site coldness	6	0
Injection site cyst	5	0
Injection site deformation	1	0
Injection site discharge	1	0
Injection site discolouration	7	0
Injection site discomfort	18	0
Injection site dryness	1	0
Injection site erythema	566	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	2	0
Injection site haemorrhage	15	0
Injection site hypersensitivity	4	0
Injection site hypoaesthesia	15	0
Injection site indentation	17	0
Injection site induration	9	0
Injection site inflammation	60	0
Injection site injury	4	0
Injection site irritation	4	0
Injection site joint discomfort	1	0
Injection site joint erythema	8	0
Injection site joint pain	35	0
Injection site joint swelling	1	0
Injection site mass	1370	0
Injection site movement impairment	5	0
Injection site muscle weakness	1	0
Injection site necrosis	6	0
Injection site nerve damage	1	0
Injection site nodule	4	0
Injection site oedema	26	0
Injection site pain	4307	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site papule	2	0
Injection site paraesthesia	25	0
Injection site pruritus	281	0
Injection site rash	294	0
Injection site reaction	118	0
Injection site scab	4	0
Injection site scar	6	0
Injection site swelling	238	0
Injection site thrombosis	1	0
Injection site ulcer	1	0
Injection site urticaria	38	0
Injection site vesicles	13	0
Injection site warmth	346	0
Interactions		
Drug interaction	32	0
Food interaction	1	0
Inhibitory drug interaction	12	0
Mass conditions NEC		
Cyst	23	0
Mass	79	0
Nodule	18	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	7	0
Mucosal inflammation	9	0
Mucosal pain	2	0
Mucosal ulceration	1	0
Oedema mucosal	3	0
Polyp	3	0
Necrosis NEC		
Fat necrosis	2	0
Necrosis	8	0
Oedema NEC		
Face oedema	31	0
Localised oedema	10	0
Oedema	69	0
Oedema peripheral	134	0
Pain and discomfort NEC		
Axillary pain	708	0
Chest discomfort	1903	0
Chest pain	4744	1
Discomfort	517	0
Facial discomfort	20	0
Facial pain	253	0
Hernia pain	2	0
Inflammatory pain	19	0
Non-cardiac chest pain	37	0
Pain	15678	0
Suprapubic pain	1	0
Tenderness	1779	0
Visceral pain	2	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	119	0
Adverse event	33	0
Adverse reaction	51	0
Diet failure	1	0
Drug ineffective	157	1
Drug intolerance	7	0
Idiosyncratic drug reaction	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	25	0
No reaction on previous exposure to drug	71	0
Remission not achieved	1	0
Similar reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	3	0
Therapeutic product effect delayed	1	0
Therapeutic product effect incomplete	1	0
Therapeutic product effect prolonged	1	0
Therapeutic product ineffective	4	0
Therapeutic reaction time decreased	1	0
Therapeutic response decreased	1	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	145	0
Therapy non-responder	3	0
Treatment failure	6	0
Vaccination failure	32	0
Vaccine positive rechallenge	1	0
<i>Trophic disorders</i>		
Atrophy	4	0
Calcinosis	2	0
Dysplasia	2	0
<i>Ulcers NEC</i>		
Ulcer	41	0
Ulcer haemorrhage	2	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	18	0
Shoulder injury related to vaccine administration	44	0
Vaccination site atrophy	1	0
Vaccination site bruising	129	0
Vaccination site coldness	1	0
Vaccination site cyst	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	11	0
Vaccination site discomfort	44	0
Vaccination site dryness	1	0
Vaccination site erythema	681	0
Vaccination site extravasation	1	0
Vaccination site granuloma	8	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	7	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	25	0
Vaccination site induration	68	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site inflammation	50	0
Vaccination site injury	4	0
Vaccination site irritation	13	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	4	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	14	0
Vaccination site joint pain	48	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	527	0
Vaccination site movement impairment	74	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	1940	0
Vaccination site papule	3	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	103	0
Vaccination site rash	181	0
Vaccination site reaction	23	0
Vaccination site scab	2	0
Vaccination site scar	6	0
Vaccination site swelling	482	0
Vaccination site urticaria	11	0
Vaccination site vesicles	9	0
Vaccination site warmth	369	0
Vascular complications associated with device		
Vascular stent occlusion	1	0
Vascular stent thrombosis	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	83	0
General disorders SOC TOTAL	237257	332

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	28	0
Cholangitis	4	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	11	0
Cholelithiasis	13	0
<i>Cholestasis and jaundice</i>		
Cholestasis	5	0
Jaundice	46	0
Jaundice cholestatic	10	0
Ocular icterus	1	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
Gallbladder oedema	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	14	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	8	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	6	0
Subacute hepatic failure	3	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	7	0
<i>Hepatic vascular disorders</i>		
Budd-Chiari syndrome	1	1
Hepatic artery thrombosis	1	0
Hepatic haemorrhage	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	0
Hepatic vein thrombosis	12	0
Portal hypertension	2	0
Portal vein phlebitis	1	0
Portal vein thrombosis	56	5
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	60	0
Hepatomegaly	3	0
Liver tenderness	6	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	4	0
Drug-induced liver injury	1	0
Hepatic necrosis	1	0
Hepatic steatosis	6	0
Hepatitis	23	0
Hepatitis acute	6	1
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0
Liver injury	18	0
Reye's syndrome	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Biliary obstruction	1	0
Sphincter of Oddi dysfunction	3	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders Hepatic disorders cont'd		
Hepatic disorders SOC TOTAL	375	8

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	24	0
<i>Allergic conditions NEC</i>		
Allergic oedema	19	0
Allergy to animal	1	0
Allergy to arthropod sting	3	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	2	0
Hypersensitivity	1312	0
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	15	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	5	0
Type IV hypersensitivity reaction	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	2	0
Allergy to chemicals	7	0
Allergy to vaccine	56	0
Contrast media reaction	4	0
Drug hypersensitivity	61	0
Food allergy	29	0
Oral allergy syndrome	3	0
Reaction to colouring	1	0
Reaction to excipient	13	0
Reaction to preservatives	15	0
Rubber sensitivity	1	0
Smoke sensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	631	2
Anaphylactic shock	111	0
Anaphylactoid reaction	22	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	2	0
Seasonal allergy	99	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	38	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Endocrine autoimmune disorders</i>		
Hashitoxicosis	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	33	0
Cytokine release syndrome	1	0
Cytokine storm	4	0
Haemophagocytic lymphohistiocytosis	8	0
Immune system disorder	26	0
Immune-mediated adverse reaction	9	0

Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Immunisation reaction	1	0
Pre-engraftment immune reaction	1	0
Sensitisation	30	0
Immunodeficiency disorders NEC		
Immunodeficiency	6	0
Immunosuppression	4	0
Transplant rejections		
Corneal graft rejection	2	0
Transplant rejection	7	0
Vasculitides		
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	0
Eosinophilic granulomatosis with polyangiitis	1	0
Immune system disorders SOC TOTAL	2661	2

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal infection	1	0
Abdominal wall infection	1	0
Anal abscess	1	0
Appendicitis	31	0
Appendicitis perforated	3	0
Diarrhoea infectious	4	0
Diverticulitis	24	0
Dysentery	4	0
Gastric infection	1	0
Gastroenteritis	35	0
Gastrointestinal infection	5	0
Large intestine infection	2	0
Peritonitis	2	0
<i>Adenoviral infections</i>		
Adenovirus infection	1	0
<i>Bacillary infections</i>		
Bacillus infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	5	0
Bacterial infection	29	1
Bacterial vaginosis	3	0
Cellulitis	486	1
Cellulitis orbital	1	0
Ear infection bacterial	2	0
Endocarditis bacterial	2	0
Eye infection bacterial	1	0
Folliculitis	9	0
Gangrene	1	0
Injection site cellulitis	7	0
Perichondritis	1	0
Periorbital cellulitis	5	0
Pneumonia bacterial	5	1
Post procedural cellulitis	1	0
Skin bacterial infection	6	0
Urinary tract infection bacterial	4	0
Vaccination site cellulitis	21	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	3	0
Bursitis infective	2	0
Intervertebral discitis	2	0
Osteomyelitis	2	1
<i>Bordetella infections</i>		
Pertussis	3	0
<i>Borrelial infections</i>		
Erythema migrans	2	0
Lyme disease	8	0
Relapsing fever	1	0
<i>Breast infections</i>		
Mastitis	36	0
<i>Brucella infections</i>		

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Brucellosis	1	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
<i>Campylobacter infections</i>		
Campylobacter colitis	1	0
Campylobacter gastroenteritis	1	0
<i>Candida infections</i>		
Anal candidiasis	2	0
Balanitis candida	1	0
Candida infection	69	0
Oral candidiasis	52	0
Skin candida	2	0
Vulvovaginal candidiasis	54	0
<i>Cardiac infections</i>		
Endocarditis	4	0
<i>Central nervous system and spinal infections</i>		
Cavernous sinus thrombosis	7	0
Central nervous system infection	1	0
Encephalitis	35	0
Encephalomyelitis	2	0
Extradural abscess	1	0
Meningitis	25	0
Myelitis	13	0
<i>Chlamydial infections</i>		
Chlamydial infection	1	0
<i>Clostridia infections</i>		
Clostridium difficile colitis	3	0
Clostridium difficile infection	2	0
Tetanus	3	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	4	0
COVID-19	474	23
COVID-19 pneumonia	32	9
Coronavirus infection	4	0
Post-acute COVID-19 syndrome	4	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	37	0
<i>Corynebacteria infections</i>		
Diphtheria	2	0
<i>Coxiella infections</i>		
Q fever	112	0
<i>Coxsackie viral infections</i>		
Coxsackie bronchitis	1	0
<i>Cytomegaloviral infections</i>		
Encephalitis cytomegalovirus	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	4	0
Gingival abscess	7	0
Gingivitis	26	0
Lip infection	1	0
Oral infection	1	0
Oral pustule	3	0
Parotitis	13	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	1	0
Sialoadenitis	2	0
Tongue abscess	4	0
Tooth abscess	14	0
Tooth infection	11	0
Ear infections		
Ear infection	114	0
Labyrinthitis	148	0
Mastoiditis	3	0
Otitis externa	5	0
Otitis media	19	0
Otosalpingitis	1	0
Ectoparasitic infestations		
Acarodermatitis	7	0
Infestation	1	0
Trombidiasis	2	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	2	0
Infectious mononucleosis	47	0
Escherichia infections		
Escherichia infection	2	0
Escherichia sepsis	2	0
Eye and eyelid infections		
Conjunctivitis	74	0
Eye infection	29	0
Eyelid boil	3	0
Eyelid infection	3	0
Hordeolum	33	0
Keratouveitis	1	0
Retinitis	2	0
Female reproductive tract infections		
Endometritis	1	0
Pelvic inflammatory disease	1	0
Pyometra	1	1
Vaginal abscess	2	0
Vaginal infection	5	0
Flaviviral infections		
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1	0
Fungal infections NEC		
Ear infection fungal	2	0
Fungal infection	21	0
Fungal skin infection	9	0
Oral fungal infection	1	0
Overgrowth fungal	1	0
Severe asthma with fungal sensitisation	4	0
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	4	0
Hepatitis virus infections		
Hepatitis E	1	0
Hepatobiliary and spleen infections		

Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Biliary sepsis	5	1
Herpes viral infections		
Eczema herpeticum	3	0
Genital herpes	59	0
Genital herpes simplex	1	0
Haemorrhagic varicella syndrome	1	0
Herpes dermatitis	2	0
Herpes ophthalmic	14	0
Herpes simplex	38	0
Herpes simplex reactivation	3	0
Herpes virus infection	15	0
Herpes zoster	1335	0
Herpes zoster oticus	12	0
Herpes zoster reactivation	2	0
Meningoencephalitis herpetic	1	0
Nasal herpes	15	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	9	0
Oral herpes	656	0
Varicella	34	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	38	0
Abscess limb	21	0
Abscess soft tissue	2	0
Catheter site infection	1	0
Coinfection	1	0
Device related infection	2	0
Genital abscess	1	0
Groin infection	1	0
Infected bite	3	0
Infected cyst	4	0
Infection	447	3
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	20	0
Localised infection	101	0
Lymph gland infection	4	0
Lymph node abscess	1	0
Omphalitis	1	0
Pathogen resistance	3	0
Pyuria	1	0
Respiratory tract infection	6	0
Toxic shock syndrome	1	0
Vaccination site abscess	4	0
Vaccination site infection	23	0
Vestibulitis	3	0
Wound abscess	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	1	0
Infectious transmissions		
Secondary transmission	14	0

Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Vaccine virus shedding	1	0
Influenza viral infections		
H1N1 influenza	1	0
H2N2 influenza	3	0
Influenza	6512	0
Klebsiella infections		
Pneumonia klebsiella	1	0
Lower respiratory tract and lung infections		
Atypical pneumonia	2	0
Bronchitis	21	0
Infectious pleural effusion	4	0
Infective exacerbation of bronchiectasis	1	0
Infective pulmonary exacerbation of cystic fibrosis	1	1
Lower respiratory tract infection	259	3
Pleural infection	1	0
Pneumonia	212	19
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	5	0
Orchitis	3	0
Mumps viral infections		
Mumps	9	0
Muscle and soft tissue infections		
Muscle abscess	2	0
Soft tissue infection	5	0
Orthopox viral infections		
Cow pox	1	0
Papilloma viral infections		
Papilloma viral infection	1	0
Paravaccinia infections		
Paravaccinia	1	0
Phleboviral infections		
Severe fever with thrombocytopenia syndrome	2	0
Plasmodia infections		
Malaria	6	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	1	0
Prion-associated disorders		
Creutzfeldt-Jakob disease	4	0
Retroviral infections		
Acquired immunodeficiency syndrome	2	0
HIV infection	1	0
HIV-associated neurocognitive disorder	1	0
Rotaviral infections		
Rotavirus infection	1	0
Rubella viral infections		
Rubella	1	0
Rubeola viral infections		
Measles	5	0
Salmonella infections		
Typhoid fever	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Abdominal sepsis	1	0

Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Bacteraemia	1	0
Neutropenic sepsis	8	0
Sepsis	87	10
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	11	0
Septic shock	4	1
Urosepsis	9	1
Viraemia	4	0
Skin structures and soft tissue infections		
Carbuncle	1	0
Dermatitis infected	10	0
Eczema infected	1	0
Impetigo	8	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	21	0
Rash pustular	18	0
Skin infection	63	0
Subcutaneous abscess	8	0
Vaccination site pustule	5	0
Staphylococcal infections		
Furuncle	47	0
Staphylococcal bacteraemia	2	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	3	1
Toxic shock syndrome staphylococcal	2	0
Vulvovaginitis staphylococcal	1	0
Streptococcal infections		
Cellulitis streptococcal	1	0
Erysipelas	1	0
Meningitis pneumococcal	2	1
Pharyngitis streptococcal	9	0
Scarlet fever	1	0
Streptococcal infection	2	0
Tonsillitis streptococcal	1	0
Tinea infections		
Body tinea	3	0
Tinea cruris	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	1	0
Treponema infections		
Neurosyphilis	1	0
Syphilis	3	0
Trypanosomal infections		
African trypanosomiasis	6	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Erythema induratum	1	0
Lymph node tuberculosis	3	0
Meningitis tuberculous	1	0
Pulmonary tuberculosis	2	0

Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Tuberculosis	4	0
Upper respiratory tract infections		
Acute sinusitis	4	0
Chronic sinusitis	14	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	29	0
Nasal vestibulitis	1	0
Nasopharyngitis	1726	0
Pharyngeal abscess	1	0
Pharyngitis	34	0
Rhinitis	48	0
Sinobronchitis	1	0
Sinusitis	334	0
Tonsillitis	75	0
Tracheitis	1	0
Upper respiratory tract infection	8	0
Urinary tract infections		
Cystitis	85	0
Genitourinary tract infection	1	0
Kidney infection	49	0
Pyelonephritis	5	0
Pyelonephritis acute	1	0
Pyelonephritis chronic	1	0
Renal abscess	1	0
Urinary tract infection	209	0
Vascular infections		
Haematoma infection	2	0
Infected lymphocele	1	0
Infected varicose vein	1	0
Lymphangitis	6	0
Viral infections NEC		
Arthritis viral	2	0
Bronchitis viral	1	0
Ear infection viral	1	0
Encephalitis viral	7	0
Eye infection viral	1	0
Gastritis viral	1	0
Gastroenteritis viral	66	0
Gastrointestinal viral infection	1	0
Hepatitis viral	2	0
Meningitis viral	17	0
Pleurisy viral	1	0
Pneumonia viral	8	1
Post viral fatigue syndrome	107	0
Sweating fever	726	0
Vestibular neuronitis	30	0
Viral diarrhoea	4	0
Viral infection	74	0
Viral labyrinthitis	7	0
Viral myocarditis	1	0
Viral pericarditis	3	0
Viral pharyngitis	30	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name		Total	Fatal
Infections	Infections cont'd		
Viral rash		75	0
Viral sepsis		1	0
Viral sinusitis		1	0
Viral tonsillitis		1	0
Infections SOC TOTAL		16539	79

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 23-Jun-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Abdomen crushing	3	0
Colon injury	1	0
Lip injury	2	0
Mouth injury	1	0
Oral contusion	12	0
Palate injury	2	0
Splenic rupture	4	0
Tongue injury	3	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	16	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	3	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	4	0
Sedation complication	4	0
<i>Atmospheric pressure injuries</i>		
Barotrauma	1	0
Decompression sickness	2	0
Hypobarism	2	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	2	0
Cartilage injury	1	0
Joint injury	9	0
Synovial rupture	2	0
<i>Cardiac and vascular procedural complications</i>		
Deep vein thrombosis postoperative	1	0
Ischaemic contracture of the left ventricle	1	0
Vascular access site bruising	1	0
Vascular graft occlusion	1	0
Vascular graft thrombosis	1	0
Vascular pseudoaneurysm	1	0
Vasoplegia syndrome	1	0
<i>Cardiovascular injuries</i>		
Heart injury	4	0
Vascular injury	8	0
Venous injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	12	0
Brain herniation	4	0
Concussion	7	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	1
Subdural haemorrhage	4	0
<i>Chemical injuries</i>		
Chemical burn	1	0
Chemical burn of oral cavity	2	0
Chemical burn of skin	4	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Chemical phlebitis	2	0
Chest and respiratory tract injuries NEC		
Chest crushing	12	0
Chest injury	1	0
Foreign body in throat	1	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	66	0
Frostbite	1	0
Cranial nerve injuries		
Cranial nerve injury	1	0
Optic nerve injury	2	0
Vth nerve injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	12	0
Exposure via breast milk	46	0
Foetal exposure during pregnancy	45	0
Maternal exposure before pregnancy	3	0
Maternal exposure during breast feeding	1178	0
Maternal exposure during pregnancy	265	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	4	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to household chemicals	1	0
Exposure to toxic agent	1	0
Exposure to vaccinated person	1	0
Eye injuries NEC		
Cataract traumatic	1	0
Eye contusion	48	0
Eye injury	31	0
Eyelid contusion	5	0
Foreign body in eye	1	0
Hyphaema	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Periorbital haemorrhage	1	0
Retinal injury	4	0
Superficial injury of eye	1	0
Traumatic iritis	1	0
Fractures and dislocations NEC		
Fracture	1	0
Joint dislocation	9	0
Multiple fractures	2	0
Stress fracture	4	0
Gastrointestinal and hepatobiliary procedural complications		
Peripancreatic fluid collection	1	0
Procedural nausea	26	0
Procedural vomiting	7	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0

Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Heat exhaustion	4	0
Heat illness	4	0
Heat oedema	13	0
Heat stroke	8	0
Intentional product misuses		
Intentional product misuse	6	0
Intentional product use issues		
Intentional product use issue	1	0
Limb fractures and dislocations		
Ankle fracture	3	0
Atypical femur fracture	1	0
Clavicle fracture	18	0
Femoral neck fracture	2	0
Femur fracture	2	0
Foot fracture	1	0
Humerus fracture	1	0
Lower limb fracture	2	0
Patella fracture	1	0
Tibia fracture	1	0
Upper limb fracture	2	0
Wrist fracture	2	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	7	0
Device use issue	1	0
Dose calculation error	2	0
Drug titration error	1	0
Inadequate aseptic technique in use of product	2	0
Intercepted medication error	5	0
Medication error	75	0
Prescription drug used without a prescription	2	0
Product use issue	5	0
Vaccination error	9	0
Wrong device used	1	0
Wrong drug	5	0
Wrong schedule	1	0
Wrong technique in product usage process	7	0
Muscle, tendon and ligament injuries		
Epicondylitis	19	0
Ligament injury	3	0
Ligament rupture	1	0
Ligament sprain	17	0
Muscle injury	43	0
Muscle rupture	17	0
Muscle strain	45	0
Post-traumatic neck syndrome	3	0
Repetitive strain injury	2	0
Tendon injury	4	0
Tendon rupture	13	0
Nerve injuries NEC		
Nerve injury	105	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	8	0
Procedural dizziness	32	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Non-occupational environmental exposures</i>		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	2	0
<i>Non-site specific injuries NEC</i>		
Animal bite	1	0
Arthropod bite	5	0
Arthropod sting	11	0
Bite	1	0
Child maltreatment syndrome	1	0
Electric shock	28	0
Fall	228	0
Inflammation of wound	3	0
Injury	12	0
Internal injury	1	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Road traffic accident	2	0
Soft tissue injury	5	0
Sports injury	1	0
Tissue injury	2	0
Traumatic haematoma	3	0
Traumatic shock	1	0
Wound	8	0
Wound complication	14	0
Wound haemorrhage	10	0
Wound secretion	3	0
<i>Non-site specific procedural complications</i>		
Administration related reaction	2	0
Incision site erythema	1	0
Incision site haemorrhage	1	0
Incision site oedema	1	0
Incision site pain	9	0
Infusion related reaction	20	0
Injection related reaction	606	0
Needle fatigue	1	0
Post procedural complication	35	0
Post procedural contusion	2	0
Post procedural discomfort	1	0
Post procedural haematoma	1	0
Procedural hypertension	1	0
Procedural pain	7	0
Procedural site reaction	1	0
Suture related complication	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Off label uses</i>		
Off label use	24	0
<i>Overdoses NEC</i>		
Intentional overdose	7	0
Overdose	23	0
Prescribed overdose	1	0
<i>Pathways and sources of exposure</i>		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Exposure via body fluid	1	0
Exposure via partner	1	0
Exposure via unknown route	1	0
Peripheral nerve injuries		
Brachial plexus injury	2	0
Median nerve injury	2	0
Sciatic nerve injury	1	0
Ulnar nerve injury	3	0
Poisoning and toxicity		
Alcohol poisoning	3	0
Chemical poisoning	1	0
Metal poisoning	2	0
Poisoning	5	0
Systemic toxicity	1	0
Toxicity to various agents	10	0
Product administration errors and issues		
Accidental overdose	4	0
Accidental underdose	2	0
Contraindicated product administered	4	0
Duplicate therapy error	2	0
Expired product administered	26	0
Extra dose administered	7	0
Inappropriate schedule of product administration	30	0
Incomplete course of vaccination	3	0
Incorrect dose administered	9	0
Incorrect product administration duration	2	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	37	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	16	0
Product administered to patient of inappropriate age	22	0
Product administration error	19	0
Product dose omission issue	4	0
Wrong patient received product	1	0
Wrong product administered	17	0
Product confusion errors and issues		
Product label confusion	1	0
Product name confusion	2	0
Product dispensing errors and issues		
Product dispensing error	14	0
Product monitoring errors and issues		
Documented hypersensitivity to administered product	1	0
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	9	0
Product prescribing error	4	0
Product selection errors and issues		
Product selection error	2	0
Product storage errors and issues in the product use system		
Intercepted product storage error	1	0
Product storage error	6	0
Product transcribing errors and communication issues		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product communication issue	1	0
Radiation injuries		
Sunburn	48	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Kidney rupture	1	0
Reproductive system and breast injuries		
Penile contusion	2	0
Uterine rupture	1	0
Reproductive tract and breast procedural complications		
Postmastectomy lymphoedema syndrome	1	0
Respiratory tract and thoracic cavity procedural complications		
Pulmonary oil microembolism	2	0
Site specific injuries NEC		
Back injury	7	0
Central nervous system injury	1	0
Face crushing	1	0
Face injury	2	0
Head injury	36	0
Limb crushing injury	8	0
Limb injury	229	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	3	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	2839	0
Hair injury	1	0
Nail injury	1	0
Scar	26	0
Scratch	4	0
Skin abrasion	5	0
Skin injury	17	0
Skin laceration	1	0
Skin pressure mark	1	0
Skin wound	6	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Recall phenomenon	1	0
Spinal cord injuries NEC		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury	1	0
Spinal cord injury sacral	1	0
Spinal fractures and dislocations		
Spinal compression fracture	3	0
Spinal fracture	5	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
Stoma site haemorrhage	1	0
Stoma site pain	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Stoma site rash	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	4	0
Burn oral cavity	11	0
Burns second degree	10	0
Cold burn	3	0
Thermal burn	47	0
Thermal burns of eye	45	0
Transplantation complications		
Transplant failure	1	0
Underdoses NEC		
Intentional underdose	1	0
Underdose	9	0
Vaccination related complications		
Adverse event following immunisation	4	0
Post vaccination syndrome	1	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	93	0
Injuries SOC TOTAL	7330	1

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Blood cortisol	1	0
Cortisol decreased	1	0
Cortisol increased	2	0
<i>Adrenal medulla tests</i>		
Epinephrine increased	1	0
Norepinephrine increased	2	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	7	0
Audiogram	1	0
<i>Autoimmunity analyses</i>		
Antimitochondrial antibody positive	1	0
Antineutrophil cytoplasmic antibody	1	0
Antinuclear antibody positive	1	0
Antiphospholipid antibodies	2	0
Antiphospholipid antibodies positive	1	0
Cold agglutinins positive	1	0
DNA antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	4	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test	1	0
Staphylococcus test positive	1	0
Treponema test positive	1	0
<i>Blood counts NEC</i>		
Blood count	9	0
Blood count abnormal	5	0
Full blood count	7	0
Full blood count abnormal	2	0
Full blood count decreased	3	0
Full blood count increased	1	0
<i>Blood gas and acid base analyses</i>		
Blood gases	1	0
Blood lactic acid	2	0
Blood lactic acid increased	5	0
Blood pH	15	0
Blood pH increased	14	0
Carbon dioxide increased	1	0
Oxygen consumption	1	0
Oxygen saturation	24	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	178	2
<i>Blood grouping and cross-matching analyses</i>		
Blood group O	2	0
Blood grouping	1	0
Rhesus antigen negative	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Scan lymph nodes	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	19	0
Blood glucose abnormal	18	0
Blood glucose decreased	37	0
Blood glucose fluctuation	31	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood glucose increased	179	0
Glycosylated haemoglobin increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur	26	0
Heart sounds	16	0
Heart sounds abnormal	8	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	3	0
Ejection fraction decreased	2	0
Myocardial strain	17	0
Stroke volume decreased	2	0
Venous pressure jugular increased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
Prostatic specific antigen decreased	1	0
Prostatic specific antigen increased	2	0
Central nervous system histopathology procedures		
Biopsy brain	1	0
Central nervous system imaging procedures		
Brain scan abnormal	1	0
Computerised tomogram head	21	0
Magnetic resonance imaging head	42	0
Scan brain	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF cell count abnormal	1	0
CSF pressure	4	0
CSF white blood cell count increased	1	0
Chemistry analyses NEC		
Histamine abnormal	3	0
Histamine level	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	7	0
Cholesterol analyses		
Blood cholesterol increased	11	0
Low density lipoprotein	1	0
Low density lipoprotein increased	1	0
Very low density lipoprotein decreased	1	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time prolonged	124	0
Anti factor VIII antibody positive	1	0
Bleeding time	7	0
Bleeding time abnormal	3	0
Bleeding time prolonged	5	0
Blood fibrinogen decreased	7	0
Blood fibrinogen increased	2	0
Blood thromboplastin	1	0
Blood thromboplastin abnormal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Clot retraction	1	0
Coagulation factor	1	0
Coagulation factor VIII level decreased	4	0
Coagulation time	8	0
Coagulation time prolonged	11	0
Coagulation time shortened	4	0
Fibrin D dimer	1	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	44	0
International normalised ratio	2	0
International normalised ratio abnormal	10	0
International normalised ratio decreased	39	0
International normalised ratio fluctuation	4	0
International normalised ratio increased	84	0
Prothrombin level increased	1	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
Digestive enzymes		
Amylase increased	1	0
Lipase increased	1	0
Pancreatic enzymes increased	1	0
ECG investigations		
Cardiac telemetry	1	0
Electrocardiogram	6	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	2	0
Electrocardiogram ST-T segment abnormal	7	0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	16	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	31	0
Faecal analyses NEC		
Faecal calprotectin	1	0
Faecal calprotectin increased	9	0
Occult blood	1	0
Stool analysis abnormal	2	0
Fertility analyses		
Semen volume decreased	2	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate	1	0
Fungus identification and serology		
Fungal test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	4	0
Stomach scan	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH	1	0
Gastric pH decreased	2	0
Gastrointestinal stoma output increased	1	0
Swallow study	3	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood gastrin	1	0
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin abnormal	1	0
Blood insulin decreased	2	0
Blood insulin increased	3	0
<i>Haematological analyses NEC</i>		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	2	0
Haematology test abnormal	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate	1	0
Red blood cell sedimentation rate increased	7	0
<i>Heart rate and pulse investigations</i>		
Brachial pulse decreased	1	0
Femoral pulse	1	0
Heart rate	1003	0
Heart rate abnormal	51	0
Heart rate decreased	113	0
Heart rate increased	1930	0
Heart rate irregular	181	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	6	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	25	0
Pulse absent	4	0
Pulse pressure increased	3	0
Pulse waveform abnormal	1	0
Radial pulse	1	0
Sinus rhythm	5	0
<i>Histopathology procedures NEC</i>		
Smear test	2	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	8	0
Computerised tomogram normal	1	0
Magnetic resonance imaging	1	0
Magnetic resonance imaging whole body	1	0
Scan	1	0
X-ray	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin A increased	1	0
Blood immunoglobulin E	1	0
Blood immunoglobulin E increased	2	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<i>Immunology analyses NEC</i>		
Antibody test	2	0
Antibody test abnormal	1	0
Antibody test negative	6	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Immunology test	8	0
Immunology test normal	1	0
Mast cell degranulation present	1	0
Neutralising antibodies	1	0
Immunology skin tests NEC		
Allergy alert test	2	0
Skin test positive	4	0
Investigations NEC		
APACHE II score	1	0
Blood test	43	0
Blood test abnormal	53	0
Laboratory test	1	0
Polymerase chain reaction positive	2	0
Quality of life decreased	3	0
Liver function analyses		
Alanine aminotransferase increased	22	0
Aspartate aminotransferase increased	3	0
Bile output	3	0
Blood bilirubin	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	13	0
Liver function test	3	0
Liver function test abnormal	39	0
Liver function test increased	9	0
Transaminases increased	9	0
Metabolism tests NEC		
Blood ketone body	10	0
Blood uric acid increased	3	0
Ubiquinone	4	0
Ubiquinone decreased	2	0
Urine ketone body present	2	0
Microbiology and serology tests NEC		
Blood culture	2	0
Blood culture negative	1	0
Septic screen	1	0
Mineral and electrolyte analyses		
Blood calcium	1	0
Blood calcium increased	1	0
Blood cyanide	1	0
Blood iron	10	0
Blood iron decreased	13	0
Blood iron increased	1	0
Blood magnesium decreased	3	0
Blood phosphorus abnormal	1	0
Blood phosphorus decreased	6	0
Blood phosphorus increased	3	0
Blood potassium decreased	9	0
Blood potassium increased	8	0
Blood sodium	2	0
Blood sodium decreased	4	0
Blood zinc increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Serum ferritin	1	0
Serum ferritin decreased	2	0
Serum ferritin increased	3	0
Sweat test	2	0
Urine copper	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone densitometry	1	0
Skull X-ray	8	0
X-ray of pelvis and hip	1	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count	2	0
Swollen joint count increased	2	0
Tender joint count	3	0
<i>Mycobacteria identification and serology</i>		
Interferon gamma release assay positive	2	0
Tuberculin test	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	17	0
Electromyogram abnormal	3	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	14	0
Nerve conduction studies abnormal	1	0
Sensory level abnormal	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	2	0
Intraocular pressure increased	6	0
Intraocular pressure test	8	0
Visual tracking test	1	0
<i>Physical examination procedures and organ system status</i>		
Body height decreased	1	0
Body surface area	3	0
Body temperature	1005	0
Body temperature abnormal	81	0
Body temperature decreased	132	0
Body temperature fluctuation	173	0
Body temperature increased	1086	0
Body temperature normal	3	0
Breath sounds	3	0
Breath sounds abnormal	5	0
Dermatologic examination abnormal	1	0
General physical condition abnormal	4	0
Grip strength	7	0
Grip strength decreased	32	0
Head lag	18	0
Lymph node palpable	5	0
Male genital examination abnormal	1	0
Menstruation normal	3	0
Muscle strength abnormal	4	0
Neurological examination	1	0
Neurological examination normal	1	0
Ophthalmological examination	2	0
Palpatory finding abnormal	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Product residue present	3	0
Psoriasis area severity index decreased	1	0
Psoriasis area severity index increased	1	0
Respiratory rate	10	0
Respiratory rate decreased	25	0
Respiratory rate increased	76	0
Skin temperature	172	0
Temperature difference of extremities	7	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	165	0
Weight increased	38	0
Pituitary analyses anterior		
Blood corticotrophin	1	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone	1	0
Blood thyroid stimulating hormone decreased	3	0
Blood thyroid stimulating hormone increased	3	0
Platelet analyses		
Platelet count	2	0
Platelet count abnormal	1	0
Platelet count decreased	273	0
Platelet count increased	6	0
Platelet count normal	1	0
Plateletcrit	1	0
Protein analyses NEC		
C-reactive protein abnormal	2	0
C-reactive protein increased	19	0
Protein total	2	0
Protein total increased	1	0
Red blood cell analyses		
Haematocrit	9	0
Haematocrit decreased	1	0
Haematocrit increased	2	0
Haemoglobin	6	0
Haemoglobin decreased	13	0
Haemoglobin increased	1	0
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	2	0
Red blood cell count	2	0
Red blood cell count decreased	3	0
Red blood cell morphology abnormal	1	0
Renal function analyses		
Blood creatine increased	1	0
Blood creatinine abnormal	1	0
Blood creatinine decreased	2	0
Blood creatinine increased	3	0
Blood urea	6	0
Blood urea increased	1	0
Glomerular filtration rate decreased	3	0
Reproductive hormone analyses		
17 ketosteroids urine decreased	1	0
Anti-Muellerian hormone level decreased	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood oestrogen increased	1	0
Blood testosterone decreased	1	0
Dihydrotestosterone decreased	1	0
False negative pregnancy test	4	0
Human chorionic gonadotropin decreased	1	0
Pregnancy test	15	0
Pregnancy test false positive	1	0
Pregnancy test negative	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	1	0
Reproductive organ and breast imaging procedures		
Mammogram	1	0
Ultrasound scan vagina normal	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume	2	0
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	12	0
Forced expiratory volume normal	1	0
Forced vital capacity decreased	2	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	3	0
Pulmonary function test decreased	4	0
Slow vital capacity	1	0
Total lung capacity decreased	3	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	2	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	17	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0
Ventilation/perfusion scan	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	6	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	1	0
Troponin	2	0
Troponin I increased	1	0
Troponin T	1	0
Troponin T increased	1	0
Special sense investigations NEC		
Olfactory test	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	17	0
Analgesic drug level increased	1	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	3	0
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
Antidepressant drug level decreased	1	0
Drug level increased	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0
Thyroxine	1	0
Thyroxine abnormal	1	0
Tri-iodothyronine decreased	7	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Lactate dehydrogenase urine increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood aluminium	1	0
Blood arsenic normal	1	0
Blood cannabinoids	1	0
Blood carbon monoxide increased	2	0
Blood heavy metal test	1	0
Blood lead	1	0
Drug screen positive	4	0
<i>Urinalysis NEC</i>		
Blood urine	34	0
Blood urine present	77	0
Cells in urine	2	0
Crystal urine	3	0
Medication crystals in urine present	1	0
Protein urine	2	0
Protein urine present	1	0
Red blood cells urine	1	0
Urea urine increased	1	0
Urine analysis	1	0
Urine analysis abnormal	13	0
Urine analysis normal	3	0
White blood cells urine positive	1	0
pH urine	9	0
pH urine decreased	2	0
pH urine increased	2	0
<i>Urinary tract function analyses NEC</i>		
Urine output	45	0
Urine output decreased	18	0
Urine output increased	10	0
<i>Urinary tract imaging procedures</i>		
Cystoscopy	2	0
<i>Vascular auscultatory investigations</i>		
Abdominal bruit	1	0
Carotid bruit	1	0
<i>Vascular imaging procedures NEC</i>		
Arteriogram carotid	1	0
Venogram	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	5	0
Blood pressure decreased	82	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure increased	282	0
Blood pressure measurement	97	0
Blood pressure normal	5	0
Blood pressure systolic	1	0
Blood pressure systolic increased	5	0
Capillary nail refill test	1	0
Pulmonary arterial pressure abnormal	1	0
<i>Virus identification and serology</i>		
Coronavirus test	38	0
Cytomegalovirus test	1	0
HIV antibody negative	2	0
Hepatitis B core antibody positive	1	0
Herpes virus test	1	0
Human papilloma virus test positive	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	6	0
SARS-CoV-2 antibody test negative	20	0
SARS-CoV-2 antibody test positive	3	0
SARS-CoV-2 test	22	0
SARS-CoV-2 test false negative	4	0
SARS-CoV-2 test false positive	3	0
SARS-CoV-2 test negative	16	0
SARS-CoV-2 test positive	90	0
Viral test	4	0
Viral test positive	1	0
<i>Vitamin analyses</i>		
Blood folate	2	0
Blood folate decreased	4	0
Vitamin B12	1	0
Vitamin B12 decreased	2	0
Vitamin D	2	0
Vitamin D decreased	4	0
Vitamin D increased	1	0
<i>Water and electrolyte analyses NEC</i>		
Blood electrolytes decreased	1	0
Blood osmolarity	1	0
Volume blood	7	0
<i>White blood cell analyses</i>		
CD4 lymphocytes decreased	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	4	0
Lymphocyte count	2	0
Lymphocyte count decreased	5	0
Lymphocyte count increased	3	0
Mononuclear cell count abnormal	1	0
Neutrophil count	3	0
Neutrophil count decreased	16	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	18	0
White blood cell count decreased	31	0
White blood cell count increased	8	0
Investigations SOC TOTAL	9694	2

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	37	0
Decreased appetite	6191	0
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	20	0
Food refusal	36	0
Hyperphagia	7	0
Hypophagia	32	0
Increased appetite	58	0
Salt craving	4	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	2	0
Hypocalcaemia	6	0
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	88	0
Diabetes mellitus inadequate control	28	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	20	0
Type 2 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	34	2
Diabetic ketosis	5	0
Euglycaemic diabetic ketoacidosis	1	0
<i>Diabetic complications neurological</i>		
Hyperglycaemic hyperosmolar nonketotic syndrome	1	0
<i>Disorders of purine metabolism</i>		
Gout	154	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	3	0
Fluid imbalance	1	0
Hyperosmolar state	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	8	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	10	0
<i>Fluid intake increased</i>		
Polydipsia	13	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	10	0
Dairy intolerance	1	0
Food intolerance	12	0
Gluten sensitivity	3	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	55	0
Abnormal weight gain	23	0
Cachexia	2	0
Feeding disorder	186	0
Food aversion	55	0
Neonatal insufficient breast milk syndrome	3	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Obesity	1	0
Overweight	2	0
Poor feeding infant	11	0
Starvation	1	0
Underweight	2	0
Weight loss poor	2	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	127	0
Insulin resistance	8	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	2	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	95	0
Hypoglycaemia unawareness	3	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	10	0
Iron excess		
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Lipoedema	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	1	0
Ketosis	4	0
Lactic acidosis	2	0
Metabolic acidosis	10	0
Metabolic disorders NEC		
Hypometabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	3	0
Phosphorus metabolism disorders		
Hypophosphataemia	2	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	4	0
Hypokalaemic syndrome	1	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	2	0
Hyponatraemia	21	0
Hyponatraemic syndrome	4	1
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	6	0
Total fluid volume decreased		
Dehydration	638	0
Hypovolaemia	1	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Total fluid volume increased</i>		
Fluid overload	7	0
Fluid retention	68	1
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	2	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	6	0
Vitamin B12 deficiency	5	0
Metabolic disorders SOC TOTAL	8190	4

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	425	0
Arthritis enteropathic	1	0
Arthropathy	30	0
Autoimmune arthritis	8	0
Haemarthrosis	7	0
Oligoarthritis	1	0
Palindromic rheumatism	5	0
Polyarthritis	14	0
Rheumatic fever	5	0
Sacroiliitis	3	0
<i>Bone disorders NEC</i>		
Bone disorder	3	0
Bone erosion	1	0
Bone loss	1	0
Exostosis	1	0
Jaw disorder	5	0
Medial tibial stress syndrome	8	0
Osteitis	9	0
Osteonecrosis of jaw	3	0
Spinal disorder	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	993	0
Bone swelling	6	0
Coccydynia	6	0
Pain in jaw	565	0
Pubic pain	1	0
Spinal pain	235	0
<i>Bursal disorders</i>		
Bursitis	130	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	63	0
Osteochondrosis	1	0
Polychondritis	1	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	2	0
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	67	0
Reynold's syndrome	6	0
Scleroderma	2	0
Sjogren's syndrome	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	2	0
Gouty tophus	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Finger deformity	3	0
Foot deformity	3	0
Hand deformity	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Knee deformity	1	0
Limb deformity	8	0
Wrist deformity	2	0
Fractures NEC		
Osteoporotic fracture	2	0
Intervertebral disc disorders NEC		
Intervertebral disc degeneration	2	0
Intervertebral disc protrusion	7	0
Joint related disorders NEC		
Ankle impingement	1	0
Femoroacetabular impingement	2	0
Joint ankylosis	2	0
Joint contracture	1	0
Joint instability	2	0
Joint laxity	5	0
Joint lock	44	0
Ligament laxity	1	0
Patellofemoral pain syndrome	6	0
Periarthritis	291	0
Rotator cuff syndrome	60	0
Temporomandibular joint syndrome	17	0
Joint related signs and symptoms		
Arthralgia	21331	0
Jaw clicking	5	0
Joint effusion	7	0
Joint noise	44	0
Joint range of motion decreased	4	0
Joint stiffness	395	0
Joint swelling	833	0
Joint vibration	5	0
Joint warmth	32	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	10	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	33	0
Metabolic bone disorders		
Dwarfism	1	0
Osteopenia	2	0
Osteoporosis	11	0
Muscle infections and inflammations		
Myositis	37	0
Myositis ossificans	1	0
Polymyositis	1	0
Muscle pains		
Fibromyalgia	249	0
Myalgia	25536	0
Myalgia intercostal	2	0
Myofascial pain syndrome	22	0
Muscle related signs and symptoms NEC		
Haematoma muscle	3	0
Muscle atrophy	23	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Muscle discomfort	18	0
Muscle disorder	8	0
Muscle fatigue	914	0
Muscle haemorrhage	3	0
Muscle mass	10	0
Muscle oedema	2	0
Muscle spasms	2865	0
Muscle swelling	29	0
Muscle tightness	174	0
Muscle twitching	475	0
Muscle tone abnormalities		
Muscle rigidity	52	0
Nuchal rigidity	16	0
Torticollis	10	0
Trismus	52	0
Muscle weakness conditions		
Muscular weakness	1843	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	1	0
Extremity contracture	2	0
Infantile back arching	1	0
Limb mass	14	0
Mandibular mass	1	0
Mastication disorder	5	0
Mobility decreased	108	0
Muscle contracture	2	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	2106	0
Posture abnormal	2	0
Somatic dysfunction	1	0
Weight bearing difficulty	6	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	3	0
Head deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	2	0
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	8	0
Musculoskeletal and connective tissue pain and discomfort		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5410	0
Flank pain	71	0
Growing pains	8	0
Limb discomfort	2142	0
Musculoskeletal chest pain	388	0
Musculoskeletal discomfort	128	0
Musculoskeletal pain	66	0
Neck pain	2830	0
Pain in extremity	20131	0
Rheumatic disorder	18	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Myopathies		
Compartment syndrome	4	0
Muscle necrosis	1	0
Myopathy	4	0
Rhabdomyolysis	8	1
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	56	0
Spinal osteoarthritis	4	0
Psoriatic arthropathies		
Psoriatic arthropathy	26	0
Rheumatoid arthropathies		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	155	0
Rheumatoid nodule	1	0
Still's disease	5	0
Soft tissue disorders NEC		
Axillary mass	65	0
Clubbing	1	0
Fistula	2	0
Groin pain	196	0
Neck mass	22	0
Soft tissue disorder	1	0
Soft tissue mass	3	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	4	0
Scoliosis	3	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	28	0
Arthritis reactive	40	0
Axial spondyloarthritis	2	0
Spondylitis	4	0
Synovial disorders		
Synovial cyst	7	0
Synovitis	14	0
Tendon disorders		
Enthesopathy	1	0
Tendon discomfort	4	0
Tendon disorder	6	0
Tendon pain	35	0
Tendonitis	66	0
Tenosynovitis	2	0
Tenosynovitis stenosans	2	0
Trigger finger	26	0
Muscle & tissue disorders SOC TOTAL	92414	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>Anal canal neoplasms malignant</i>		
Anal cancer	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	1	0
Follicular lymphoma	1	0
<i>Bile duct neoplasms malignant</i>		
Bile duct cancer	1	0
Cholangiocarcinoma	1	0
<i>Bladder neoplasms malignant</i>		
Bladder cancer	1	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	3	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	44	0
Breast cancer in situ	1	0
Breast cancer male	3	0
Breast cancer metastatic	1	0
Breast cancer stage I	1	0
Breast cancer stage III	2	0
Intraductal proliferative breast lesion	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	4	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	2	0
Brain neoplasm malignant	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	3	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	2	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
<i>Endometrial neoplasms malignant</i>		
Clear cell endometrial carcinoma	1	0
Endometrial cancer	2	0
<i>Gastrointestinal neoplasms benign NEC</i>		
Gastrointestinal tract adenoma	1	0
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	4	0
<i>Glial tumours malignant</i>		
Glioblastoma	2	0
Glioblastoma multiforme	1	0
<i>Haematologic neoplasms NEC</i>		
Systemic mastocytosis	1	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	3	0
<i>Hepatoblastomas</i>		
Hepatoblastoma	1	0
<i>Hodgkin's disease NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Hodgkin's disease	1	0
Leiomyosarcomas		
Pleomorphic leiomyosarcoma	1	0
Leukaemias NEC		
Leukaemia	1	0
Leukaemia recurrent	1	0
Leukaemias acute NEC		
Acute leukaemia	1	0
Leukaemias acute myeloid		
Acute myeloid leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	6	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Leukaemias myeloid NEC		
Myeloid leukaemia	1	0
Lip and oral cavity neoplasms benign		
Papillary cystadenoma lymphomatosum	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer	1	0
Squamous cell carcinoma of the oral cavity	2	0
Lymphomas unspecified NEC		
Lymphoma	14	0
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Epstein Barr virus positive mucocutaneous ulcer	1	0
Histiocytic necrotising lymphadenitis	1	0
Lymphoproliferative disorder	1	0
Lymphoproliferative disorder in remission	1	0
Mediastinal neoplasms malignancy unspecified NEC		
Good syndrome	3	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to central nervous system	1	1
Metastases to liver	1	0
Metastases to lung	1	1
Metastases to unknown and unspecified sites		
Metastasis	3	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	1	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms benign site unspecified NEC		
Adenoma benign	1	0
Fibroma	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma	2	0
Metastatic neoplasm	3	0
Neoplasm malignant	7	1
Squamous cell carcinoma	2	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm recurrence	6	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	4	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Meningioma	3	0
Schwannoma	1	0
Neuromas		
Acoustic neuroma	5	0
Non-Hodgkin's lymphomas NEC		
Cutaneous lymphoma	1	0
Non-Hodgkin's lymphoma	1	0
Non-small cell neoplasms malignant of the respiratory tract cell type specified		
Lung adenocarcinoma	1	1
Ocular neoplasms benign		
Eye naevus	3	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	5	0
Oesophageal carcinoma	4	0
Oesophageal squamous cell carcinoma	1	0
Oncologic complications and emergencies		
Cancer fatigue	4	0
Cancer pain	2	0
Intracranial tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	3	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	9	0
Ovarian cancer recurrent	1	0
Ovarian cancer stage IV	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	4	0
Pancreatic carcinoma metastatic	1	0
Paranasal sinus and nasal cavity neoplasms malignant and unspecified		
Nasal cavity cancer	1	0
Paraneoplastic syndromes NEC		
Paraneoplastic syndrome	1	0
Penile neoplasms malignant		
Penile cancer	1	0
Plasma cell myelomas		
Plasma cell myeloma	3	0
Plasmacytoma	1	0
Prostatic neoplasms malignant		
Prostate cancer	6	0
Renal neoplasms malignant		
Clear cell renal cell carcinoma	2	0
Metastatic renal cell carcinoma	1	0
Renal cancer	1	0
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	1	0
Respiratory tract and pleural neoplasms malignancy unspecified NEC		
Maxillofacial sinus neoplasm	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	5	0
Lung cancer metastatic	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Lung neoplasm malignant	11	0
Throat cancer	1	0
Salivary gland neoplasms malignant		
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
Skin melanomas (excl ocular)		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	2	0
Malignant melanoma in situ	1	0
Skin neoplasms benign		
Acrochordon	3	0
Anogenital warts	2	0
Haemangioma of skin	15	0
Melanocytic naevus	3	0
Seborrheic keratosis	1	0
Skin papilloma	17	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	7	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Knuckle pads	1	0
Lipoma	5	0
Uterine neoplasms benign		
Uterine leiomyoma	6	0
Uterine neoplasms malignant NEC		
Uterine cancer	2	0
Vulval neoplasms malignant		
Vulval cancer	1	0
Neoplasms SOC TOTAL	332	4

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	28	0
Extensor plantar response	2	0
Hyperreflexia	5	0
Hyporeflexia	17	0
Poor sucking reflex	3	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	23	0
<i>Absence seizures</i>		
Petit mal epilepsy	34	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	3	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	317	2
Miller Fisher syndrome	20	0
Subacute inflammatory demyelinating polyneuropathy	4	0
<i>Auditory nerve disorders</i>		
Acoustic neuritis	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	14	0
Horner's syndrome	2	0
Orthostatic intolerance	5	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery aneurysm	1	0
Carotid artery dissection	1	0
Intracranial aneurysm	1	0
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	3	0
Basal ganglia stroke	1	0
Basilar artery occlusion	1	0
Basilar artery thrombosis	2	0
Brain stem haemorrhage	3	1
Brain stem infarction	2	2
Brain stem stroke	4	2
Carotid artery occlusion	2	0
Carotid artery thrombosis	9	1
Cerebellar haemorrhage	4	0
Cerebellar infarction	4	0
Cerebellar stroke	9	0
Cerebral artery embolism	8	0
Cerebral artery occlusion	3	0
Cerebral artery thrombosis	11	0
Cerebral haematoma	12	1
Cerebral haemorrhage	149	40
Cerebral infarction	81	4
Cerebral ischaemia	3	0
Cerebral thrombosis	33	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	977	37
Embolic stroke	19	0
Haemorrhage intracranial	49	9

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Haemorrhagic cerebral infarction	3	1
Haemorrhagic stroke	35	5
Haemorrhagic transformation stroke	6	3
Internal capsule infarction	1	0
Intracranial haematoma	8	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	2	0
Ischaemic stroke	115	4
Lacunar infarction	4	0
Lacunar stroke	20	0
Pseudostroke	1	0
Spinal cord haematoma	1	0
Spinal cord infarction	1	0
Spinal stroke	2	0
Subarachnoid haemorrhage	96	4
Thalamus haemorrhage	7	0
Thrombotic stroke	10	0
Vertebral artery occlusion	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	4	0
Central nervous system inflammation	10	0
Neurosarcoidosis	3	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	1
Carotid arteriosclerosis	1	0
Carotid artery stenosis	3	0
Central nervous system vasculitis	3	0
Cerebral amyloid angiopathy	2	0
Cerebral arteriosclerosis	2	0
Cerebral congestion	3	0
Cerebral microhaemorrhage	1	0
Cerebral small vessel ischaemic disease	2	0
Cerebral vasoconstriction	2	0
Cerebrovascular disorder	3	0
Internal carotid artery deformity	1	0
Reversible cerebral vasoconstriction syndrome	3	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	184	19
Cerebral venous thrombosis	45	5
Superior sagittal sinus thrombosis	26	3
Transverse sinus thrombosis	4	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	5	0
Choreiform movements		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	4	0
Demyelinating polyneuropathy	9	0
Diabetic neuropathy	2	0
Polyneuropathy chronic	1	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Coma states		
Coma	18	0
Diabetic coma	3	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	34	0
Balance disorder	781	0
Cerebellar ataxia	2	0
Cerebellar syndrome	1	0
Coordination abnormal	111	0
Dysdiadochokinesis	1	0
Dysstasia	103	0
Hand-eye coordination impaired	1	0
Nystagmus	21	0
Cortical dysfunction NEC		
Agraphia	1	0
Alexia	5	0
Aphasia	129	0
Apraxia	1	0
Dysgraphia	6	0
Dyslexia	2	0
Dyspraxia	5	0
Neurologic neglect syndrome	3	0
Visuospatial deficit	2	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Neurovascular conflict	1	0
Paresis cranial nerve	2	0
Dementia (excl Alzheimer's type)		
Dementia	23	0
Dementia with Lewy bodies	1	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	4	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	9	0
Demyelination	15	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	14	0
Consciousness fluctuating	4	0
Depressed level of consciousness	80	0
Hypoglycaemic unconsciousness	1	0
Lethargy	4568	0
Loss of consciousness	966	0
Postictal state	1	0
Sedation	14	0
Somnolence	1786	1
Stupor	8	0
Syncope	2336	0
Disturbances in sleep phase rhythm		
Advanced sleep phase	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Circadian rhythm sleep disorder	5	0
Delayed sleep phase	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
Non-24-hour sleep-wake disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	10	0
Ballismus	1	0
Bradykinesia	28	0
Clumsiness	44	0
Dyskinesia	104	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	14	0
Hyperkinesia	27	0
Hypokinesia	62	0
Meige's syndrome	1	0
Motor dysfunction	14	0
Movement disorder	88	0
Psychomotor hyperactivity	36	0
Tardive dyskinesia	1	0
Dystonias		
Dystonia	18	0
Dystonic tremor	3	0
Opisthotonus	4	0
Writer's cramp	1	0
Encephalitis NEC		
Bickerstaff's encephalitis	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	4	0
Encephalopathies NEC		
Autoimmune encephalopathy	3	1
Encephalopathy	5	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	3	0
Encephalopathies toxic and metabolic		
Hepatic encephalopathy	2	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	6	0
Microvascular cranial nerve palsy	2	0
VIth nerve paralysis	8	0
Facial cranial nerve disorders		
Bell's palsy	448	0
Facial nerve disorder	5	0
Facial paralysis	267	0
Facial paresis	134	0
Facial spasm	31	0
Oculofacial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	80	0
Headaches NEC		
Cervicogenic headache	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Chronic paroxysmal hemicrania	1	0
Cluster headache	671	0
Cold-stimulus headache	74	0
Drug withdrawal headache	15	0
Exertional headache	11	0
External compression headache	4	0
Headache	76904	4
Medication overuse headache	16	0
New daily persistent headache	19	0
Occipital neuralgia	19	0
Ophthalmoplegic migraine	1	0
Post-traumatic headache	3	0
Primary cough headache	2	0
Primary headache associated with sexual activity	12	0
Sinus headache	907	0
Tension headache	1411	0
Thunderclap headache	44	0
Vascular headache	72	0
Hydrocephalic conditions		
Hydrocephalus	12	0
Hypoglossal nerve disorders		
Tongue paralysis	5	0
Increased intracranial pressure disorders		
Brain compression	3	0
Brain oedema	23	1
Cerebrospinal fluid circulation disorder	3	0
Cytotoxic oedema	1	0
Idiopathic intracranial hypertension	6	0
Intracranial pressure increased	19	0
Intellectual disabilities		
Intellectual disability	9	0
Lumbar spinal cord and nerve root disorders		
Lumbar radiculopathy	2	0
Sciatica	173	0
Memory loss (excl dementia)		
Amnesia	294	0
Memory impairment	269	0
Transient global amnesia	20	0
Meningitis NEC		
Meningitis noninfective	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	150	1
Disturbance in attention	618	0
Judgement impaired	3	0
Mental impairment	117	0
Migraine headaches		
Basilar migraine	4	0
Hemiplegic migraine	36	0
Migraine	6861	0
Migraine with aura	340	0
Migraine without aura	43	0
Ophthalmic migraine	12	0
Retinal migraine	72	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Status migrainosus	5	0
Typical aura without headache	16	0
Vestibular migraine	26	0
Mixed cranial nerve disorders		
Bulbar palsy	1	0
Mononeuropathies		
Carpal tunnel syndrome	27	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	2	0
Nerve compression	46	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	10	0
Piriformis syndrome	3	0
Radial nerve palsy	2	0
Sciatic nerve neuropathy	3	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Multiple sclerosis acute and progressive		
Band sensation	5	0
Multiple sclerosis	51	0
Multiple sclerosis relapse	46	0
Relapsing multiple sclerosis	1	0
Uhthoff's phenomenon	4	0
Muscle tone abnormal		
Hypertonia	2	0
Hypotonia	32	0
Serotonin syndrome	1	0
Stiff leg syndrome	8	0
Myelitis (incl infective)		
Myelitis transverse	66	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	184	0
Narcolepsy	19	0
Nervous system cysts and polyps		
Pineal gland cyst	1	0
Nervous system disorders NEC		
Brain stem syndrome	2	0
Central nervous system lesion	2	0
Cerebral disorder	2	0
Microglial nodules	1	0
Nervous system disorder	45	0
Neurotoxicity	2	0
Psychomotor skills impaired	4	0
Neurologic visual problems NEC		
Hemianopia	6	0
Hemianopia homonymous	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Tunnel vision	18	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	20770	0
Dizziness exertional	92	0
Dizziness postural	2035	1
Drooling	21	0
Exaggerated startle response	4	0
Fontanelle bulging	3	0
Head discomfort	645	0
Hyporesponsive to stimuli	2	0
Inability to crawl	1	0
Infant irritability	5	0
Intracranial hypotension	2	0
Meningism	2	0
Myoclonus	26	0
Neurological decompensation	4	0
Neurological symptom	96	0
Patient elopement	2	0
Persistent postural-perceptual dizziness	29	0
Pleocytosis	3	0
Presyncope	566	0
Sensory overload	11	0
Slow response to stimuli	6	0
Tongue biting	8	0
Unresponsive to stimuli	88	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Muscle contractions involuntary	34	0
Muscle spasticity	25	0
Neuromuscular pain	6	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	12	0
Myasthenia gravis crisis	3	0
Olfactory nerve disorders		
Anosmia	274	0
Hyposmia	10	0
Parosmia	369	0
Optic nerve disorders NEC		
Optic neuritis	43	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	28	0
Burning sensation	840	0
Burning sensation mucosal	3	0
Dysaesthesia	8	0
Formication	69	0
Hand-arm vibration syndrome	1	0
Hemianaesthesia	4	0
Hemiparaesthesia	2	0
Hyperaesthesia	252	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Hypoaesthesia	5069	0
Lhermitte's sign	1	0
Paraesthesia	8442	0
Reversed hot-cold sensation	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	29	0
Hemiparesis	90	0
Hemiplegia	34	0
Monoparesis	84	0
Monoplegia	111	0
Paralysis	270	0
Paraparesis	6	0
Paraplegia	2	0
Paresis	6	0
Peripheral nerve palsy	1	0
Postictal paralysis	2	0
Quadriparesis	1	0
Quadriplegia	3	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	153	0
Parkinson's disease	15	0
Parkinsonism	10	0
Reduced facial expression	7	0
Vascular parkinsonism	1	0
Partial complex seizures		
Dreamy state	21	0
Focal dyscognitive seizures	6	0
Temporal lobe epilepsy	4	0
Partial simple seizures NEC		
Autonomic seizure	2	0
Simple partial seizures	7	0
Peripheral neuropathies NEC		
Autoimmune neuropathy	2	0
Axonal neuropathy	1	0
Ischaemic neuropathy	1	0
Neuralgic amyotrophy	6	0
Neuritis	12	0
Neuropathy peripheral	182	0
Peripheral motor neuropathy	1	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	13	0
Polyneuropathy	10	0
Small fibre neuropathy	2	0
Thoracic outlet syndrome	1	0
Seizures and seizure disorders NEC		
Alcoholic seizure	1	0
Atonic seizures	10	0
Change in seizure presentation	7	0
Clonic convulsion	9	0
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	2	0
Epilepsy	277	0
Epileptic aura	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Febrile convulsion	91	0
Migraine-triggered seizure	2	0
Myoclonic epilepsy	4	0
Partial seizures	53	0
Psychogenic seizure	5	0
Seizure	1152	2
Seizure anoxic	3	0
Seizure cluster	8	0
Seizure like phenomena	2	0
Status epilepticus	126	3
Tonic clonic movements	3	0
Tonic convulsion	35	0
Sensory abnormalities NEC		
Ageusia	982	0
Allodynia	57	0
Aura	24	0
Central pain syndrome	2	0
Complex regional pain syndrome	10	0
Decreased vibratory sense	1	0
Dysgeusia	1913	0
Electric shock sensation	81	0
Hypogeusia	5	0
Intercostal neuralgia	2	0
Loss of proprioception	3	0
Neuralgia	1182	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	18	0
Post herpetic neuralgia	11	0
Restless arm syndrome	11	0
Restless legs syndrome	352	0
Sensory disturbance	113	0
Sensory loss	194	0
Taste disorder	482	0
Vibratory sense increased	1	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	2	0
Periodic limb movement disorder	1	0
Sleep deficit	47	0
Speech and language abnormalities		
Dysarthria	355	0
Incoherent	16	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Slow speech	34	0
Speech disorder	83	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	5	0
Myelopathy	3	0
Radicular pain	1	0
Radiculitis brachial	17	0
Radiculopathy	2	0
Spinal cord disorder	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Spinal cord oedema	1	0
Structural brain disorders NEC		
Brain injury	26	2
Cerebral mass effect	8	0
Intracranial mass	3	0
White matter lesion	2	0
Transient cerebrovascular events		
Transient ischaemic attack	402	0
Tremor (excl congenital)		
Action tremor	2	0
Asterixis	1	0
Essential tremor	5	0
Head titubation	18	0
Intention tremor	1	0
Postural tremor	1	0
Resting tremor	6	0
Tremor	9336	2
Trigeminal disorders		
Facial neuralgia	37	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	5	0
Trigeminal neuralgia	84	0
Trigeminal neuritis	2	0
Trigeminal palsy	1	0
Vagus nerve disorders		
Vagus nerve paralysis	1	0
Vocal cord paralysis	2	0
Vertigos NEC		
Vertigo CNS origin	2	0
Nervous system disorders SOC TOTAL	163821	165

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	112	1
<i>Foetal complications NEC</i>		
Foetal disorder	2	0
Foetal hypokinesia	1	0
<i>Foetal position and presentation abnormalities</i>		
Face presentation	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	2	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	4	0
Premature rupture of membranes	1	0
Prolonged labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	1	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	5	0
Hyperemesis gravidarum	2	0
Morning sickness	34	0
Pelvic girdle pain	1	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Pregnancy	25	0
Uterine contractions during pregnancy	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	6	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	0
Stillbirth	2	1
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	4	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	1	0
Pregnancy with contraceptive patch	1	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	4	0
Pregnancy conditions SOC TOTAL	226	2

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Reaction Name	Total	Fatal
<i>Counterfeit, falsified and substandard products</i>		
Suspected counterfeit product	1	0
<i>Device electrical issues</i>		
Device electrical impedance issue	1	0
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device issues NEC</i>		
Device issue	4	0
Device leakage	2	0
<i>Device malfunction events NEC</i>		
Oversensing	25	0
Stent malfunction	1	0
Thrombosis in device	46	0
Undersensing	4	0
<i>Device physical property and chemical issues</i>		
Needle issue	10	0
Syringe issue	1	0
<i>Manufacturing facilities and equipment issues</i>		
Manufacturing equipment issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	1	0
<i>Product distribution and storage issues</i>		
Product temperature excursion issue	3	0
<i>Product label issues</i>		
Product barcode issue	1	0
Product label issue	2	0
<i>Product packaging issues</i>		
Product container issue	2	0
<i>Product physical issues</i>		
Product colour issue	2	0
Product leakage	1	0
Product odour abnormal	3	0
Product physical issue	1	0
Product taste abnormal	8	0
<i>Product quality issues NEC</i>		
Product formulation issue	1	0
Product origin unknown	2	0
Product quality issue	1	0
Suspected product quality issue	3	0
null SOC TOTAL	128	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	20	0
Breath holding	4	0
Sexually inappropriate behaviour	1	0
Staring	10	0
<i>Abnormal food elimination</i>		
Self-induced vomiting	1	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	5	0
Adjustment disorder with mixed anxiety and depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	10	0
Blunted affect	1	0
Constricted affect	7	0
Flat affect	9	0
Inappropriate affect	17	0
<i>Amnesic symptoms</i>		
Paramnesia	5	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
Generalised anxiety disorder	2	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	181	0
Anxiety	1010	0
Immunisation anxiety related reaction	1	0
Nervousness	565	0
Procedural anxiety	1	0
Stress	113	0
Tension	63	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	16	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	12	0
Antisocial behaviour	1	0
Asocial behaviour	1	0
Aversion	1	0
Disinhibition	1	0
Impatience	2	0
Indifference	8	0
Paranoia	38	0
Personality change	8	0
Social avoidant behaviour	5	0
Soliloquy	3	0
Violence-related symptom	3	0
<i>Bipolar disorders</i>		
Bipolar I disorder	6	0
Bipolar disorder	3	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Change in sustained attention	1	0
Daydreaming	13	0
Distractibility	2	0
Mental fatigue	430	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	5	0
Speech sound disorder	2	0
<i>Confusion and disorientation</i>		
Confusional state	1904	0
Disorientation	671	0
<i>Decreased physical activity levels</i>		
Catatonia	2	0
<i>Deliria</i>		
Delirium	455	0
Delirium febrile	3	0
<i>Delusional disorders</i>		
Alice in wonderland syndrome	3	0
<i>Delusional symptoms</i>		
Delusion	45	1
Delusion of parasitosis	2	0
Mixed delusion	1	0
Thought withdrawal	1	0
<i>Dementia NEC</i>		
Pseudodementia	1	0
<i>Depressive disorders</i>		
Agitated depression	3	0
Depression	540	0
Depression suicidal	14	0
Major depression	21	0
Mixed anxiety and depressive disorder	2	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	16	0
Dissociation	66	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	40	0
Insomnia	2850	0
Middle insomnia	71	0
Terminal insomnia	17	0
<i>Dyssomnias</i>		
Dyssomnia	4	0
Poor quality sleep	619	0
<i>Eating disorders NEC</i>		
Eating disorder	11	0
Pica	1	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	73	0
Dysphoria	2	0
Emotional disorder	89	0
Emotional distress	67	0
Emotional poverty	2	0
Euphoric mood	60	0
Frustration tolerance decreased	9	0
Irritability	288	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Mood altered	71	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	1	0
Agoraphobia	3	0
Fear	43	0
Fear of death	16	0
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	2	0
Fear of open spaces	1	0
Performance fear	1	0
Phobia	3	0
Phonophobia	3	0
Social fear	1	0
Thanatophobia	1	0
Fluctuating mood symptoms		
Mood swings	93	0
Hallucinations (excl sleep-related)		
Hallucination	878	0
Hallucination, auditory	42	0
Hallucination, olfactory	11	0
Hallucination, tactile	1	0
Hallucination, visual	53	0
Hallucinations, mixed	8	0
Somatic hallucination	1	0
Impulse control disorders		
Clinomania	1	0
Impulse-control disorder	2	0
Impulsive behaviour	1	0
Intermittent explosive disorder	1	0
Increased physical activity levels		
Restlessness	454	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Emotional disorder of childhood	1	0
Mental disorders NEC		
Mental disorder	17	0
Mental status changes	3	0
Mental disorders due to a general medical condition NEC		
Mental disorder due to a general medical condition	1	0
Neuropsychiatric symptoms	2	0
Mood alterations with depressive symptoms		
Anhedonia	4	0
Decreased interest	12	0
Depressed mood	577	0
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	17	0
Negative thoughts	8	0
Sense of a foreshortened future	2	0
Tearfulness	98	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	30	0
<i>Mood disorders NEC</i>		
Affective disorder	3	0
Apathy	58	0
Laziness	1	0
Listless	119	0
Mood disorder due to a general medical condition	1	0
Substance-induced mood disorder	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	4	0
Sleep attacks	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Body dysmorphic disorder	2	0
Compulsive shopping	2	0
Dermatillomania	1	0
Obsessive thoughts	3	0
Obsessive-compulsive disorder	2	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	3	0
Female orgasmic disorder	1	0
Orgasm abnormal	1	0
Orgasmic sensation decreased	4	0
Premature ejaculation	2	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	271	0
Panic disorder	3	0
Panic reaction	35	0
<i>Paraphilias and paraphilic disorders</i>		
Fetishism	2	0
<i>Parasomnias</i>		
Abnormal dreams	351	0
Abnormal sleep-related event	2	0
Confusional arousal	3	0
Exploding head syndrome	6	0
Nightmare	425	0
Parasomnia	1	0
Rapid eye movements sleep abnormal	4	0
Sleep inertia	1	0
Sleep talking	16	0
Sleep terror	58	0
Sleep-related eating disorder	2	0
Somnambulism	10	0
<i>Perception disturbances NEC</i>		
Autoscopy	25	0
Deja vu	4	0
Delusional perception	2	0
Derealisation	14	0
Flashback	2	0
Illusion	11	0
Near death experience	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Pseudohallucination	1	0
Time perception altered	5	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	49	0
Psychiatric symptoms NEC		
Helplessness	2	0
Hypervigilance	13	0
Psychiatric symptom	7	0
Psychological trauma	4	0
Psychotic disorder NEC		
Acute psychosis	4	0
Psychotic behaviour	2	0
Psychotic disorder	37	0
Psychotic symptom	1	0
Rebound psychosis	1	0
Schizoaffective and schizophreniform disorders		
Schizoaffective disorder	1	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	3	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	16	0
Libido increased	8	0
Loss of libido	37	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	362	0
Sleep disorder due to a general medical condition	1	0
Sleep disorder due to general medical condition, insomnia type	2	0
Somatic symptom disorders		
Conversion disorder	19	0
Habit cough	37	0
Illness anxiety disorder	1	0
Psychogenic tremor	2	0
Somatic symptom disorder	1	0
Speech and language usage disturbances		
Disorganised speech	18	0
Logorrhoea	3	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
Speech articulation and rhythm disturbances		
Dysphemia	27	0
Lack of spontaneous speech	3	0
Stereotypies and automatisms		
Bruxism	33	0
Head banging	42	0
Waxy flexibility	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Stress disorders</i>		
Acute stress disorder	2	0
Burnout syndrome	12	0
Hyperarousal	3	0
Post-traumatic stress disorder	14	0
<i>Substance related and addictive disorders</i>		
Alcohol abuse	2	0
Alcohol use disorder	2	0
Alcoholic hangover	1	0
Alcoholism	3	0
Dependence	2	0
Drug abuse	1	0
Drug dependence	1	0
Substance abuse	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	3	3
Intentional self-injury	8	0
Self-injurious ideation	2	0
Suicidal behaviour	3	0
Suicidal ideation	98	0
Suicide attempt	25	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	84	0
Confabulation	1	0
Illogical thinking	1	0
Impaired reasoning	3	0
Intrusive thoughts	6	0
Morbid thoughts	4	0
Tachyphrenia	23	0
Thinking abnormal	24	0
Thought blocking	5	0
<i>Tic disorders</i>		
Secondary tic	1	0
Tic	13	0
Psychiatric disorders SOC TOTAL	15592	4

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	7	0
Bladder irritation	7	0
Bladder pain	56	0
Bladder spasm	1	0
Dysuria	75	0
Incontinence	69	0
Micturition disorder	3	0
Micturition frequency decreased	1	0
Micturition urgency	96	0
Mixed incontinence	1	0
Pollakiuria	267	0
Urethral pain	6	0
Urge incontinence	2	0
Urinary hesitation	6	0
Urinary incontinence	106	0
Urinary retention	75	0
Urine flow decreased	17	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	16	0
Urinary bladder haemorrhage	10	1
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	8	0
Cystitis noninfective	3	0
Lupus cystitis	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	6	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	2	0
Glomerulonephritis membranoproliferative	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	4	0
Henoch-Schonlein purpura nephritis	1	0
IgA nephropathy	3	0
Nephrotic syndrome	14	0
<i>Myoneurogenic bladder disorders</i>		
Automatic bladder	1	0
Bladder dysfunction	5	0
Hypertonic bladder	14	0
Loss of bladder sensation	10	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	5	0
Tubulointerstitial nephritis	5	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	2	0
<i>Renal disorders NEC</i>		
Oedematous kidney	1	0
Renal disorder	10	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal haemorrhage	2	0
Renal failure and impairment		
Acute kidney injury	53	1
Anuria	5	0
Chronic kidney disease	9	0
End stage renal disease	1	0
Oliguria	10	0
Renal failure	29	3
Renal impairment	14	0
Renal injury	4	0
Renal hypertension and related conditions		
Hypertensive nephropathy	1	0
Renal lithiasis		
Nephrolithiasis	16	0
Renal obstructive disorders		
Hydronephrosis	1	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Renal atrophy	2	0
Renal vascular and ischaemic conditions		
Renal artery occlusion	1	0
Renal embolism	1	0
Renal infarct	12	1
Renal tubular injury	1	0
Renal vascular thrombosis	1	0
Renal vein embolism	1	0
Renal vein occlusion	2	0
Renal vein thrombosis	8	0
Structural and obstructive urethral disorders (excl congenital)		
Urethral spasm	1	0
Ureteric disorders NEC		
Ureteral disorder	2	0
Urinary abnormalities		
Chromaturia	93	0
Glycosuria	1	0
Haematuria	57	0
Microalbuminuria	1	0
Proteinuria	8	0
Urine abnormality	17	0
Urine odour abnormal	20	0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	47	0
Nocturia	20	0
Polyuria	32	0
Renal colic	2	0
Renal pain	875	0
Urinary tract discomfort	1	0
Urinary tract pain	14	0
Renal & urinary disorders SOC TOTAL	2292	6

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	7	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	5	0
Breast mass	50	0
Gynaecomastia	9	0
Mammary duct ectasia	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	3	0
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	7	0
Breast discolouration	1	0
Breast discomfort	10	0
Breast engorgement	6	0
Breast haemorrhage	1	0
Breast induration	1	0
Breast oedema	1	0
Breast pain	385	0
Breast swelling	53	0
Breast tenderness	52	0
Nipple exudate bloody	1	0
Nipple pain	33	0
Nipple swelling	3	0
<i>Cervix disorders NEC</i>		
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation disorder	3	0
Ejaculation failure	4	0
Erectile dysfunction	64	0
Erection increased	5	0
Organic erectile dysfunction	18	0
Painful erection	1	0
Priapism	3	0
Retrograde ejaculation	2	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	1	0
<i>Lactation disorders</i>		
Galactorrhoea	3	0
Lactation disorder	2	0
Lactation puerperal increased	4	0
Suppressed lactation	22	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal disorder	2	0
Menopausal symptoms	32	0
Menopause delayed	3	0
Premature menopause	18	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menopausal effects on the genitourinary tract		
Postmenopausal haemorrhage	258	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	4	0
Abnormal withdrawal bleeding	4	0
Dysmenorrhoea	650	0
Intermenstrual bleeding	404	0
Menstrual discomfort	5	0
Menstrual disorder	775	0
Menstruation irregular	1079	0
Premenstrual dysphoric disorder	4	0
Premenstrual headache	4	0
Premenstrual pain	40	0
Premenstrual syndrome	19	0
Retrograde menstruation	3	0
Withdrawal bleed	11	0
Menstruation with decreased bleeding		
Amenorrhoea	284	0
Hypomenorrhoea	230	0
Menstruation delayed	1510	0
Oligomenorrhoea	52	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	2455	0
Menometrorrhagia	10	0
Polymenorrhoea	320	0
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	11	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	23	0
Ovarian and fallopian tube disorders NEC		
Fallopian tube spasm	1	0
Ovarian enlargement	1	0
Ovarian haemorrhage	3	0
Ovarian necrosis	1	0
Ovarian oedema	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	30	0
Premature ovulation	2	0
Pelvic prolapse conditions		
Pelvic prolapse	1	0
Vaginal prolapse	1	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri pain	34	0
Pelvic haematoma	1	0
Pelvic haemorrhage	20	0
Penile and scrotal infections and inflammations		
Balanoposthitis	3	0
Penile disorders NEC (excl erection and ejaculation)		
Penile blister	6	0
Penile burning sensation	1	0
Penile curvature	4	0
Penile discharge	2	0
Penile exfoliation	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Penile haemorrhage	4	0
Penile oedema	3	0
Penile pain	2	0
Penile size reduced	1	0
Penis disorder	7	0
Peyronie's disease	4	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	5	0
Prostatic neoplasms and hypertrophy		
Benign prostatic hyperplasia	2	0
Prostatic signs, symptoms and disorders NEC		
Prostatic pain	1	0
Prostatism	1	0
Prostatomegaly	3	0
Reproductive tract disorders NEC (excl neoplasms)		
Female genital tract fistula	1	0
Genital blister	3	0
Genital haemorrhage	24	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	2	0
Genital lesion	1	0
Genital paraesthesia	3	0
Genital ulceration	12	0
Perineal disorder	2	0
Varicose veins pelvic	1	0
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	2	0
Reproductive tract neoplasms NEC		
Genital cyst	2	0
Reproductive tract signs and symptoms NEC		
Genital burning sensation	8	0
Genital discomfort	3	0
Genital erythema	1	0
Genital pain	3	0
Genital rash	3	0
Pelvic discomfort	3	0
Pelvic pain	138	0
Perineal pain	1	0
Pruritus genital	7	0
Scrotal disorders NEC		
Scrotal dermatitis	1	0
Scrotal oedema	1	0
Scrotal pain	12	0
Scrotal swelling	5	0
Varicocele	1	0
Sexual function and fertility disorders NEC		
Dyspareunia	4	0
Female sexual dysfunction	1	0
Infertility	3	0
Infertility female	1	0
Infertility male	2	0
Male sexual dysfunction	1	0
Sexual dysfunction	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Spermatogenesis and semen disorders</i>		
Aspermia	2	0
Haematospermia	11	0
Semen discolouration	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular atrophy	1	0
Testicular disorder	5	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	94	0
Testicular retraction	2	0
Testicular swelling	18	0
Testis discomfort	3	0
<i>Testicular and epididymal neoplasms</i>		
Epididymal cyst	1	0
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	6	0
Endometriosis	47	0
Metrorrhoea	1	0
Uterine enlargement	1	0
Uterine haemorrhage	43	0
Uterine pain	7	0
<i>Uterine neoplasms</i>		
Uterine cyst	1	0
Uterine polyp	3	0
<i>Uterine tone disorders</i>		
Uterine spasm	16	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	13	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal disorder	1	0
Vaginal haemorrhage	834	0
Vaginal ulceration	6	0
Vulval disorder	2	0
Vulval haemorrhage	23	0
Vulval ulceration	4	0
Vulvovaginal ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	2	0
Enlarged clitoris	1	0
Labia enlarged	2	0
Vaginal discharge	58	0
Vaginal lesion	5	0
Vaginal odour	3	0
Vulval oedema	1	0
Vulvovaginal burning sensation	7	0
Vulvovaginal discomfort	7	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal dryness	8	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	29	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	10689	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	12	0
Apnoeic attack	1	0
Dyspnoea	6381	5
Dyspnoea at rest	14	0
Dyspnoea exertional	46	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	87	0
Hypopnoea	209	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	7	0
Orthopnoea	3	0
Respiration abnormal	91	0
Respiratory arrest	20	0
Respiratory distress	10	0
Respiratory fatigue	7	0
Sleep apnoea syndrome	27	0
Tachypnoea	36	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	529	0
Asthma exercise induced	1	0
Asthma late onset	2	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	2	0
Asthmatic crisis	5	0
Bronchitis chronic	1	0
Bronchospasm	16	0
Chronic obstructive pulmonary disease	40	4
Cough variant asthma	7	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	554	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Hypercapnia	1	0
Hypoxia	66	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	3601	0
Haemoptysis	121	0
Productive cough	175	0
Sputum discoloured	12	0
Sputum increased	1	0
<i>Diaphragmatic disorders</i>		
Diaphragmatic spasm	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	2	0
Vocal cord disorder	4	0

Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Respiratory disorders cont'd</i>		
Vocal cord dysfunction	1	0
Vocal cord thickening	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	2	0
Laryngospasm	3	0
Stridor	20	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	2	0
Eosinophilic pneumonia	1	0
Pneumonia aspiration	22	5
Pneumonitis	28	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	42	0
Lower respiratory tract congestion	4	0
Lung opacity	6	0
Pleuritic pain	39	0
Pulmonary haemorrhage	7	1
Pulmonary pain	201	0
Rales	2	0
<i>Mediastinal disorders</i>		
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	432	0
Nasal inflammation	8	0
Rhinitis allergic	23	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2043	0
Intranasal hypoaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	6	0
Nasal dryness	56	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	13	0
Nasal polyps	1	0
Nasal pruritus	10	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	3	0
<i>Neonatal hypoxic conditions</i>		
Cyanosis neonatal	1	0
Gasping syndrome	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	3	0
Sinonasal obstruction	10	0
Sinus congestion	82	0
Sinus disorder	13	0

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sinus polyp	2	0
Parenchymal lung disorders NEC		
Atelectasis	5	0
Emphysema	3	0
Idiopathic pulmonary fibrosis	1	0
Interstitial lung disease	17	0
Lung consolidation	7	0
Lung cyst	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	3	0
Pulmonary fibrosis	6	0
Pharyngeal disorders (excl infections and neoplasms)		
Oropharyngeal swelling	2	0
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	36	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	12	0
Pharyngeal paraesthesia	33	0
Pharyngeal swelling	257	0
Pharyngeal ulceration	14	0
Tonsillar disorder	1	0
Tonsillar erythema	6	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	62	0
Tonsillar inflammation	4	0
Tonsillar ulcer	2	0
Tonsillolith	1	0
Pleural conditions NEC		
Pleural thickening	1	0
Pleural infections and inflammations		
Lupus pleurisy	2	0
Pleurisy	43	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	32	1
Pneumothorax	7	0
Pneumothorax spontaneous	1	0
Pulmonary hypertension		
Pulmonary hypertension	3	1
Pulmonary oedemas		
Acute lung injury	1	0
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	17	0
Pulmonary oedema	26	1
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	1337	88
Pulmonary infarction	14	1
Pulmonary thrombosis	21	3
Pulmonary venous thrombosis	3	0
Respiratory failures (excl neonatal)		

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Acute respiratory failure	1	0
Respiratory failure	20	3
Respiratory signs and symptoms NEC		
Allergic respiratory symptom	10	0
Diaphragmalgia	13	0
Nasal flaring	1	0
Painful respiration	7	0
Pleural rub	1	0
Respiratory symptom	15	0
Suffocation feeling	5	0
Respiratory tract disorders NEC		
Aspiration	9	2
Chronic respiratory disease	2	1
Lung disorder	6	0
Pulmonary mass	3	0
Respiratory disorder	8	0
Respiratory tract congestion	7	0
Respiratory tract haemorrhage	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	2	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	1	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal fistula	1	0
Tracheal pain	4	0
Upper respiratory tract signs and symptoms		
Aphonia	89	0
Catarrh	58	0
Choking	19	0
Choking sensation	8	0
Dry throat	248	0
Dysphonia	138	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	19	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	105	0
Nasal obstruction	1	0
Oropharyngeal blistering	24	0
Oropharyngeal discomfort	35	0
Oropharyngeal pain	3948	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	64	0
Rhinalgia	32	0
Rhinorrhoea	1576	0
Sinus pain	565	0
Sneezing	453	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	189	0
Throat lesion	1	0
Throat tightness	193	0
Upper airway obstruction	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	25	0
Yawning	65	0
Vascular pulmonary disorders NEC		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	25265	118

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	100	0
Acne cystic	5	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	271	0
Alopecia areata	21	0
Alopecia scarring	2	0
Alopecia totalis	1	0
Alopecia universalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	4	0
Madarosis	2	0
<i>Angioedemas</i>		
Angioedema	320	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1619	0
Hidradenitis	1	0
Hyperhidrosis	8742	0
Hypohidrosis	3	0
Miliaria	205	0
Night sweats	1785	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	496	0
Blister rupture	7	0
Blood blister	96	0
Dermatitis bullous	13	0
Dermatitis herpetiformis	2	0
Erythema multiforme	36	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	23	0
Pemphigus	1	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	4	0
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	1	0
Cutaneous lupus erythematosus	1	0
Dermatomyositis	3	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	2	0
Dry skin	402	0
Macule	11	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	883	0
Papule	104	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Peau d'orange	3	0
Scab	25	0
Scar pain	12	0
Sensitive skin	559	0
Skin burning sensation	528	0
Skin discolouration	169	0
Skin discomfort	5	0
Skin disorder	24	0
Skin fissures	11	0
Skin fragility	2	0
Skin indentation	15	0
Skin induration	15	0
Skin laxity	1	0
Skin lesion	43	0
Skin necrosis	5	0
Skin odour abnormal	46	0
Skin plaque	3	0
Skin reaction	242	0
Skin sensitisation	85	0
Skin swelling	88	0
Skin texture abnormal	1	0
Skin tightness	32	0
Skin warm	552	0
Skin weeping	5	0
Sticky skin	7	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	167	0
Dermatitis allergic	289	0
Dermatitis atopic	23	0
Dermatitis contact	21	0
Dermatitis diaper	2	0
Dyshidrotic eczema	9	0
Eczema	266	0
Eczema asteatotic	14	0
Eczema nummular	3	0
Eczema weeping	2	0
Hand dermatitis	6	0
Intertrigo	2	0
Perioral dermatitis	5	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	9	0
Skin irritation	133	0
Stasis dermatitis	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	32	0
Drug reaction with eosinophilia and systemic symptoms	13	0
Fixed eruption	5	0
Palmar-plantar erythrodysesthesia syndrome	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Erythemas</i>		
Erythema	3180	0
Erythema ab igne	1	0
Palmar erythema	5	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	15	0
Skin exfoliation	136	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	4	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
<i>Hyperpigmentation disorders</i>		
Chloasma	1	0
Ephelides	1	0
Melanoderma	2	0
Skin hyperpigmentation	8	0
Solar lentigo	6	0
<i>Hypertrichoses</i>		
Hypertrichosis	2	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	9	0
Skin hypopigmentation	3	0
Vitiligo	18	0
<i>Lipodystrophies</i>		
Lipoatrophy	2	0
Lipohypertrophy	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Ingrowing nail	2	0
Nail bed disorder	2	0
Nail bed inflammation	1	0
Nail bed tenderness	2	0
Nail discolouration	9	0
Nail disorder	1	0
Nail growth abnormal	1	0
Nail hypertrophy	1	0
Nail necrosis	1	0
Nail pigmentation	1	0
Nail pitting	1	0
Nail ridging	6	0
Onychalgia	5	0
Onychoclasia	9	0
Onycholysis	2	0
Onychomadesis	3	0
Splinter haemorrhages	3	0
<i>Panniculitides</i>		
Erythema nodosum	31	0
Panniculitis	4	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	22	0
Lichen sclerosus	4	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Parapsoriasis	1	0
Pityriasis rosea	53	0
Pityriasis rubra pilaris	2	0
Photosensitivity and photodermatosis conditions		
Photodermatosis	2	0
Photosensitivity reaction	151	0
Polymorphic light eruption	4	0
Solar dermatitis	1	0
Pigmentation changes NEC		
Pigmentation disorder	11	0
Pilar disorders NEC		
Hair colour changes	9	0
Hair disorder	1	0
Hair growth abnormal	7	0
Hair texture abnormal	8	0
Piloerection	90	0
Pseudofolliculitis	1	0
Trichodynia	6	0
Trichorrhexis	2	0
Pruritus NEC		
Itching scar	4	0
Pruritus	7510	0
Pruritus allergic	1	0
Senile pruritus	1	0
Psoriatic conditions		
Guttate psoriasis	27	0
Palmoplantar pustulosis	1	0
Psoriasis	169	0
Pustular psoriasis	1	0
Purpura and related conditions		
Ecchymosis	5	0
Henoch-Schonlein purpura	15	0
Petechiae	306	0
Purpura	124	0
Pustular conditions		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	8	0
Rash	8134	0
Rash erythematous	2123	0
Rash macular	692	0
Rash maculo-papular	63	0
Rash morbilliform	43	0
Rash papular	522	0
Rash pruritic	1767	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	83	0
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	2	0
Granulomatous rosacea	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rosacea	37	0
Scaly conditions		
Pityriasis	10	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	10	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	10	0
Skin discharge	1	0
Skin mass	37	0
Skin and subcutaneous tissue ulcerations		
Diabetic foot	2	0
Diabetic ulcer	1	0
Pyoderma gangrenosum	2	0
Skin erosion	42	0
Skin ulcer	27	0
Skin cysts and polyps		
Dermal cyst	20	0
Skin dystrophies		
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	16	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	39	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	8	0
Skin striae	10	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	3	0
Needle track marks	3	0
Skin preneoplastic conditions NEC		
Actinic keratosis	2	0
Leukoplakia	1	0
Skin vascular conditions NEC		
Angiodermatitis	1	0
Skin oedema	3	0
Skin vasculitides		
Cutaneous vasculitis	9	0
Hypersensitivity vasculitis	3	0
Vasculitic rash	25	1
Skin vasomotor conditions		
Livedo reticularis	55	0
Telangiectasia and related conditions		
Spider naevus	4	0
Telangiectasia	3	0
Urticarias		
Chronic spontaneous urticaria	3	0
Cold urticaria	4	0
Idiopathic urticaria	8	0
Mechanical urticaria	3	0
Solar urticaria	1	0

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Reaction Name		Total	Fatal
Skin disorders	Skin disorders cont'd		
Urticaria		2260	0
Urticaria chronic		29	0
Urticaria contact		2	0
Urticaria papular		3	0
Urticaria pigmentosa		1	0
Urticaria thermal		6	0
Urticarial vasculitis		4	0
Skin disorders SOC TOTAL		46922	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	2	0
Menopause	39	0
Postmenopause	9	0
<i>Alcohol product use</i>		
Alcoholic	1	0
<i>Criminal activity</i>		
Chemical submission	1	0
<i>Dependents</i>		
Sick relative	1	0
<i>Dietary and nutritional issues</i>		
Inadequate diet	1	0
Kosher diet	1	0
<i>Disability issues</i>		
Bedridden	81	0
Breast prosthesis user	2	0
Dependence on oxygen therapy	1	0
Disability	3	0
Hearing aid user	2	0
Hearing disability	1	0
Housebound	2	0
Immobile	44	0
Immobilisation prolonged	4	0
Impaired driving ability	4	0
Impaired work ability	18	0
Loss of personal independence in daily activities	7	0
Mental disability	1	0
Paralytic disability	1	0
Physical disability	1	0
Sight disability	19	0
Sitting disability	2	0
Walking aid user	1	0
Walking disability	2	0
<i>Educational issues</i>		
Illiteracy	2	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	5	0
Stress at work	1	0
<i>Family and partner issues</i>		
Homosexual parent	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Food contamination	1	0
Water pollution	3	0
<i>Pregnancy related circumstances</i>		
Breast feeding	7	0
<i>Sexuality issues</i>		
Anal sex	1	0
Homosexuality	1	0
<i>Social issues NEC</i>		
Blood donor	2	0
Contraindication to medical treatment	1	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Contraindication to vaccination	2	0
Convalescent	1	0
Hair dye user	1	0
Impaired quality of life	1	0
Refusal of vaccination	2	0
Tanning	2	0
Tattoo	1	0
Tobacco use		
Non-tobacco user	5	0
Tobacco user	2	0
Social circumstances SOC TOTAL	295	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	3	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
COVID-19 prophylaxis	1	0
COVID-19 treatment	6	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Cerebral revascularisation	1	0
Coronary artery bypass	1	0
<i>Autonomic nerve therapeutic procedures</i>		
Vagotomy	3	0
<i>Blood and blood product treatment</i>		
Photopheresis	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
Antitussive therapy	1	0
<i>Cardiac device therapeutic procedures</i>		
Cardiac pacemaker insertion	1	0
Pacemaker generated rhythm	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Pericardial excision	2	0
<i>Contraceptive methods female</i>		
Contraception	2	0
Contraceptive diaphragm	3	0
Oral contraception	1	0
<i>Corneal and scleral therapeutic procedures</i>		
Corneal transplant	1	0
<i>Dental and gingival therapeutic procedures</i>		
Dental care	1	0
Tooth extraction	1	0
Tooth repair	2	0
<i>Dietary and nutritional therapies</i>		
Fluid replacement	1	0
Medical diet	5	0
Nothing by mouth order	5	0
<i>External ear therapeutic procedures</i>		
Cerumen removal	2	0
<i>Eye therapeutic procedures NEC</i>		
Eye irrigation	3	0
<i>Facial therapeutic procedures</i>		
Face lift	2	0
<i>Fallopian tube therapeutic procedures</i>		
Fallopian tube operation	1	0
<i>Fertility and fertilisation interventions female</i>		
Ovulation induction	2	0
<i>Gastric therapeutic procedures</i>		
Antacid therapy	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal resection	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	27	0
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	2	0
Haematological therapeutic procedures NEC		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	1	0
Head, neck and oral cavity therapeutic procedures NEC		
Neck lift	1	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	3	0
Hormone therapy	4	0
Immunisations		
COVID-19 immunisation	185	1
Immunisation	85	0
Tuberculosis immunisation	1	0
Induced abortions		
Abortion induced	1	0
Iris and ciliary body therapeutic procedures		
Pupil constriction procedure	1	0
Joint therapeutic procedures		
Hip surgery	1	0
Joint injection	2	0
Joint stabilisation	1	0
Knee operation	1	0
Large intestine therapeutic procedures		
Appendectomy	6	0
Colectomy	1	0
Limb therapeutic procedures		
Arm amputation	1	0
Foot amputation	1	0
Leg amputation	3	0
Limb immobilisation	25	0
Limb operation	10	0
Limb reattachment surgery	1	0
Toe amputation	4	0
Mastectomies		
Breast conserving surgery	2	0
Muscle therapeutic procedures		
Muscle relaxant therapy	2	0
Nail therapeutic procedures		
Nail operation	1	0
Nasal therapeutic procedures		
Nasal irrigation	1	0
Nervous system therapeutic procedures NEC		
Central nervous system stimulation	3	0
Orbit and globe therapeutic procedures		
Eye muscle operation	1	0
Patient positioning		
Prone position	1	0
Peripheral nerve therapeutic procedures		
Carpal tunnel decompression	1	0

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	3	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Antidepressant therapy	1	0
Psychotherapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	1	0
Skin lesion excisions		
Tattoo excision	1	0
Small intestine therapeutic procedures		
Ileostomy	2	0
Spine and spinal cord therapeutic procedures		
Spinal operation	1	0
Testicular and scrotal therapeutic procedures		
Testes exploration	1	0
Therapeutic procedures NEC		
Anaphylaxis treatment	3	0
Antiallergic therapy	1	0
Bed rest	22	0
Catheter management	4	0
Catheter placement	1	0
Fatigue management	1	0
Heat therapy	2	0
Hospitalisation	24	0
Immobilisation bandage	1	0
Injection	36	0
Interchange of vaccine products	3	0
Localised alternating hot and cold therapy	6	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	1	0
Occupational therapy	1	0
Physical fitness training	4	0
Physiotherapy	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Stoma care	1	0
Surgery	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0
Transgender operation	1	0
Tumour excision	1	0
Tonsillar therapeutic procedures		
Tonsillectomy	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		

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Name: COVID-19 AstraZeneca Vaccine Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Endometrial ablation	2	0
Hysterectomy	1	0
Vascular therapeutic procedures NEC		
Thrombectomy	2	0
Thrombolysis	2	0
Venous therapeutic procedures		
Phlebotomy	2	0
Surgical & medical procedures SOC TOTAL	606	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	10	0
Hypertensive emergency	2	0
Hypertensive urgency	4	0
Malignant hypertension	4	0
Tyramine reaction	1	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	9	2
Aneurysm ruptured	1	0
Artery dissection	1	0
Venous aneurysm	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	5	0
Aortic dissection	2	1
Aortic intramural haematoma	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	23	1
Aortic thrombosis	12	2
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
Aortic stenosis	2	0
<i>Arterial infections and inflammations</i>		
Arteritis	5	0
Giant cell arteritis	52	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	20	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	7	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	104	1
Distributive shock	2	0
Hypoperfusion	3	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	3	0
Shock	52	1
Shock haemorrhagic	1	0
Shock symptom	5	0
<i>Haemorrhages NEC</i>		
Bloody discharge	14	0
Haematoma	90	0
Haemorrhage	955	2
Internal haemorrhage	27	0
Venous haemorrhage	8	0
<i>Lymphangiopathies</i>		
Lymphocele	2	0
Lymphorrhoea	1	0
<i>Lymphoedemas</i>		

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Lymphoedema	60	0
Non-site specific embolism and thrombosis		
Arterial thrombosis	23	1
Atheroembolism	1	0
Embolism	255	3
Embolism arterial	2	0
Embolism venous	12	1
Microembolism	3	0
Paradoxical embolism	1	0
Thrombophlebitis migrans	1	0
Thrombosis	1374	26
Venous thrombosis	32	0
Non-site specific necrosis and vascular insufficiency NEC		
Arterial occlusive disease	14	0
Arterial spasm	2	0
Arterial stenosis	1	0
Arteriosclerosis	5	0
Haemorrhagic infarction	1	0
Infarction	8	0
Ischaemia	12	0
Peripheral venous disease	7	0
Vascular compression	1	0
Vascular occlusion	1	0
Vasospasm	10	0
Non-site specific vascular disorders NEC		
Angiopathy	2	0
Arterial rupture	1	0
Capillary fragility	9	0
Collateral circulation	1	0
Haemodynamic instability	3	0
Hyperaemia	2	0
Neovascularisation	1	0
Superficial vein prominence	5	0
Vascular pain	108	0
Vascular rupture	1	0
Vascular wall discolouration	1	0
Vasodilatation	97	0
Vein collapse	1	0
Vein discolouration	6	0
Vein disorder	18	0
Vein rupture	13	0
Peripheral aneurysms and dissections		
Peripheral artery aneurysm	1	0
Peripheral embolism and thrombosis		
Blue toe syndrome	34	0
Deep vein thrombosis	997	8
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	23	0
Pelvic venous thrombosis	16	1
Peripheral artery thrombosis	17	0
Peripheral embolism	8	0
Peripheral vein thrombus extension	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	2	0
Thrombophlebitis	114	0
Thrombophlebitis superficial	59	0
Venous thrombosis limb	3	0
Peripheral vascular disorders NEC		
Cyanosis	102	0
Erythromelalgia	6	0
Flushing	664	0
Hot flush	1986	0
Peripheral vascular disorder	4	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Dry gangrene	1	0
Extremity necrosis	2	0
Iliac artery occlusion	1	0
Intermittent claudication	3	0
Ischaemic limb pain	5	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	3	0
Peripheral artery occlusion	8	0
Peripheral coldness	1221	0
Peripheral ischaemia	32	2
Poor peripheral circulation	49	0
Raynaud's phenomenon	131	0
Phlebitis NEC		
Phlebitis	50	0
Phlebitis superficial	10	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific necrosis and vascular insufficiency NEC		
Superior vena cava syndrome	1	0
Site specific vascular disorders NEC		
Pallor	397	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	2	0
Spider vein	14	0
Varicophlebitis	7	0
Varicose ulceration	1	0
Varicose vein	123	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	5	0
Hypertension	820	0
Labile hypertension	1	0
Systolic hypertension	2	0
Venous hypertension	3	0
White coat hypertension	11	0
Vascular hypotensive disorders		
Capillary leak syndrome	8	0
Hypotension	498	0
Orthostatic hypotension	44	0
Vascular malformations and acquired anomalies		
Arteriovenous fistula	1	0

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Vascular disorders Vascular disorders cont'd		
<i>Vasculitides NEC</i>		
Behcet's syndrome	3	0
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	104	2
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	4	1
Vascular disorders SOC TOTAL	11157	57
TOTAL REACTIONS FOR DRUG	762706	936
TOTAL REPORTS	211339	
TOTAL FATAL OUTCOME REPORTS		936