

COVID-19 vaccine AstraZeneca analysis print

All UK spontaneous reports received between 4/01/21 and 14/07/21 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

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	12	0
Iron deficiency anaemia	11	0
Pernicious anaemia	4	0
<i>Anaemias NEC</i>		
Anaemia	137	0
Autoimmune anaemia	1	0
Blood loss anaemia	3	0
Hypochromic anaemia	2	0
Microcytic anaemia	1	0
Normocytic anaemia	3	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	9	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	6	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	119	0
Spontaneous haematoma	8	0
Spontaneous haemorrhage	2	0
<i>Coagulation factor deficiencies</i>		
Hypofibrinogenaemia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	9	0
Antiphospholipid syndrome	25	0
Coagulopathy	62	0
Disseminated intravascular coagulation	17	2
Hypercoagulation	23	1
Hypocoagulable state	1	0
<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	10	0
Bone marrow disorder	2	0
Bone marrow oedema	1	0
Mast cell activation syndrome	6	0
Mastocytosis	2	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	9	0
<i>Leukocytoses NEC</i>		
Leukocytosis	4	0
Lymphocytosis	9	0
Monocytosis	2	0
Neutrophilia	14	0
<i>Leukopenias NEC</i>		

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Blood disorders Blood disorders cont'd		
Leukopenia	10	0
Lymphopenia	9	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	1	0
Lymph node fibrosis	1	0
Lymph node pain	552	0
Lymphadenitis	30	0
Lymphadenopathy	4729	0
Lymphatic disorder	1	0
Pseudolymphoma	3	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	4	0
Cytopenia	1	0
Myelosuppression	5	0
Pancytopenia	19	0
Neutropenias		
Agranulocytosis	4	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	76	0
Platelet disorders NEC		
Platelet anisocytosis	3	0
Platelet disorder	8	0
Polycythaemia (excl rubra vera)		
Polycythaemia	2	0
Stress polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	3	0
Red blood cell abnormal findings NEC		
Anisocytosis	2	0
Macrocytosis	2	0
Poikilocytosis	1	0
Polychromasia	3	0
Rouleaux formation	1	0
Sickle cell trait and disorders		
Sickle cell anaemia with crisis	5	0
Spleen disorders		
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	5	0
Thrombocytopenias		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	11	0
Immune thrombocytopenia	214	1
Thrombocytopenia	843	6
Thrombocytopenic purpura	9	0
Thrombotic thrombocytopenic purpura	6	0
Thrombocytoses		

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Blood disorders Blood disorders cont'd		
Thrombocytosis	11	0
White blood cell abnormal findings NEC		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	7154	10

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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	24	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	2	0
Bundle branch block left	7	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	5	0
Cardiac disorder	69	1
Cardiac dysfunction	1	0
Cardiac ventricular thrombosis	10	2
Cardiovascular disorder	9	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	9	2
<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	14	0
Cardiovascular symptom	2	0
Palpitations	4893	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	11	1
Congestive cardiomyopathy	9	0
Stress cardiomyopathy	3	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	3	1
Coronary artery disease	7	0
Coronary artery dissection	1	0
Coronary artery embolism	1	0
Coronary artery occlusion	1	0
Coronary artery thrombosis	14	3
<i>Heart failures NEC</i>		
Cardiac failure	72	9
Cardiac failure acute	9	2
Cardiac failure chronic	1	1
Cardiac failure congestive	3	2
Cardiogenic shock	8	2
Cardiopulmonary failure	1	1
Ventricular failure	1	0

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Cardiac disorders Cardiac disorders cont'd		
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	7	0
Acute myocardial infarction	68	12
Angina pectoris	202	0
Angina unstable	15	0
Arteriospasm coronary	5	0
Microvascular coronary artery disease	2	0
Myocardial infarction	362	49
Myocardial ischaemia	22	10
Prinzmetal angina	1	0
<i>Left ventricular failures</i>		
Acute left ventricular failure	1	0
Left ventricular failure	6	1
<i>Mitral valvular disorders</i>		
Ischaemic mitral regurgitation	1	0
Mitral valve incompetence	7	0
Mitral valve prolapse	2	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	17	1
Diastolic dysfunction	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	17	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
<i>Noninfectious myocarditis</i>		
Myocarditis	76	1
<i>Noninfectious pericarditis</i>		
Pericarditis	126	0
<i>Pericardial disorders NEC</i>		
Cardiac tamponade	1	1
Pericardial effusion	24	0
Pericardial haemorrhage	5	2
Pericardial rub	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	128	2
Arrhythmia neonatal	1	0
Bradycardia	76	0
Cardiac fibrillation	6	0
Cardiac flutter	229	0
Extrasystoles	133	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	15	0
Tachyarrhythmia	11	0
Tachycardia	1206	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0

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Cardiac disorders Cardiac disorders cont'd		
Right ventricular failure	3	1
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	14	0
Atrial fibrillation	291	0
Atrial flutter	34	0
Atrial tachycardia	3	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	4	0
Sinus node dysfunction	1	0
Sinus tachycardia	66	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	38	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	155	33
Cardio-respiratory arrest	3	1
Pulseless electrical activity	5	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	11	0
Ventricular fibrillation	7	1
Ventricular tachycardia	14	0
Cardiac disorders SOC TOTAL	8682	147

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	9	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	2	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	0
<i>Coagulation disorders congenital</i>		
Factor VII deficiency	1	0
Protein C deficiency	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Foetal malformation	1	0
Young's syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	3	0
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	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	2	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	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	2	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	2	0

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Non-site specific muscle disorders congenital</i>		
Rippling muscle disease	1	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	3	0
<i>Pancreatic disorders congenital</i>		
Hereditary pancreatitis	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	12	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	2	0
<i>Sex chromosomal abnormalities</i>		
Klinefelter's syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Macroglossia	1	0
<i>Vascular anomalies congenital NEC</i>		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	77	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	31	0
Ear discomfort	106	0
Ear disorder	17	0
Ear haemorrhage	15	0
Ear pain	1957	0
Ear pruritus	5	0
Ear swelling	71	0
Otorrhoea	7	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	3	0
Eustachian tube obstruction	7	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	32	0
External ear pain	13	0
Juvenile spring eruption	1	0
Red ear syndrome	5	0
<i>External ear infections and inflammations</i>		
External ear inflammation	3	0
<i>Hearing disorders NEC</i>		
Auditory disorder	9	0
<i>Hearing losses</i>		
Deafness	335	0
Deafness bilateral	15	0
Deafness neurosensory	32	0
Deafness transitory	3	0
Deafness unilateral	49	0
Hypoacusis	216	0
Mixed deafness	1	0
Neurosensory hypoacusis	2	0
Sudden hearing loss	62	0
<i>Hyperacusia</i>		
Hyperacusis	147	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	5	0
Meniere's disease	24	0
Vestibular disorder	7	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	119	0
Phobic postural vertigo	2	0
Tinnitus	3727	0
Vertigo	1993	0
Vertigo labyrinthine	12	0
Vertigo positional	137	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	1	0
Middle ear effusion	5	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	9191	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	6	0
Thyroiditis	13	0
Thyroiditis acute	4	0
Thyroiditis chronic	1	0
Thyroiditis subacute	2	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	17	0
Adrenocortical insufficiency acute	30	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
Luteal phase deficiency	2	0
<i>Ectopic endocrine disorders</i>		
Carcinoid syndrome	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogenic effect	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
Premature menarche	15	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	17	0
Ovulation delayed	11	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	2	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	19	0
Thyroid disorder	14	0
Thyroid mass	6	0

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Endocrine disorders Endocrine disorders cont'd		
Thyroid pain	13	0
Thyroid hyperfunction disorders		
Basedow's disease	6	0
Hyperthyroidism	39	0
Thyrotoxic crisis	4	0
Thyroid hypofunction disorders		
Hypothyroidism	48	0
Thyroid neoplasms		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	318	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	11	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	46	0
Vitreous floaters	168	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	122	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
<i>Conjunctival structural change, deposit and degeneration</i>		
Conjunctival bleb	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	2	0
Ulcerative keratitis	3	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal perforation	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	130	0
Excessive eye blinking	8	0
Eyelid myokymia	2	0
Eyelid ptosis	50	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	4	0
Glaucoma	11	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	40	0
<i>Lacrimation disorders</i>		
Dry eye	286	0
Lacrimation increased	244	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	21	0
Chalazion	2	0

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Eye disorders Eye disorders cont'd		
Eczema eyelids	3	0
Erythema of eyelid	7	0
Eyelid cyst	16	0
Eyelid irritation	4	0
Eyelid margin crusting	1	0
Eyelid oedema	12	0
Eyelid rash	14	0
Meibomianitis	1	0
Swelling of eyelid	122	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid exfoliation	3	0
Eyelid skin dryness	5	0
Eyelid thickening	4	0
Growth of eyelashes	8	0
Lagophthalmos	3	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	3	0
Eye haemorrhage	101	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	3	0
<i>Ocular cysts and polyps</i>		
Vitreous cyst	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	9	0
Eye disorder	27	0
Eye oedema	16	0
Eye pain	3222	0
Eye swelling	587	0
Eye symptom	11	0
Eye ulcer	9	0
Eyelid disorder	12	0
Eyelid pain	19	0
Eyelids pruritus	10	0
Ocular discomfort	75	0
Periorbital discomfort	1	0
Periorbital oedema	16	0
Periorbital pain	4	0
Periorbital swelling	99	0
Retinal disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Autoimmune eye disorder	1	0
Eye allergy	29	0
Eye discharge	25	0
Eye inflammation	30	0
Eye irritation	199	0
Eye pruritus	289	0
Limbal swelling	7	0
Ocular hyperaemia	426	0
Ocular rosacea	1	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	12	0
Eye movement disorder	49	0
Gaze palsy	3	0

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Eye disorders Eye disorders cont'd		
Ocular myasthenia	2	0
Ophthalmoplegia	1	0
Strabismus	5	0
Ocular sensation disorders		
Abnormal sensation in eye	24	0
Asthenopia	347	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	36	0
Hypoaesthesia eye	27	0
Photophobia	1005	0
Optic disc abnormalities NEC		
Optic atrophy	1	0
Optic discs blurred	2	0
Papilloedema	13	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	2	0
Optic ischaemic neuropathy	11	0
Orbital structural change, deposit and degeneration		
Lid sulcus deepened	3	0
Pupil disorders		
Miosis	14	0
Mydriasis	31	0
Pupil fixed	12	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	17	0
Retinal infarction	1	0
Retinal ischaemia	1	0
Retinal vascular occlusion	2	0
Retinal vascular thrombosis	3	0
Retinal vein occlusion	75	0
Retinal vein thrombosis	6	0
Retinal vein varices	1	0
Retinal structural change, deposit and degeneration		
Macular cyst	1	0
Macular degeneration	8	0
Macular detachment	1	0
Macular hole	2	0
Neovascular age-related macular degeneration	11	0
Retinal detachment	23	0
Retinal drusen	1	0
Retinal tear	15	0
Retinal toxicity	6	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Vitreoretinal traction syndrome	1	0
Retinal, choroid and vitreous infections and inflammations		
Cystoid macular oedema	1	0
Macular oedema	6	0
Retinal oedema	1	0
Retinal vasculitis	1	0
Retinopathies NEC		
Acute macular outer retinopathy	4	0
Acute zonal occult outer retinopathy	1	0
Diabetic retinopathy	2	0
Retinal exudates	17	0
Retinopathy	7	0
Scleral infections, irritations and inflammations		
Episcleritis	15	0
Scleritis	11	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	6	0
Eye opacity	1	0
Visual colour distortions		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	3	0
Erythropsia	6	0
Xanthopsia	9	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Delayed dark adaptation	1	0
Diplopia	306	0
Dysmetropsia	1	0
Halo vision	13	0
Metamorphopsia	36	0
Oscillopsia	1	0
Photopsia	314	0
Scintillating scotoma	8	0
Vision blurred	2780	0
Visual brightness	10	0
Visual snow syndrome	4	0
Visual field disorders		
Visual field defect	30	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	8	0
Blindness	261	0
Blindness day	1	0
Blindness transient	23	0
Blindness unilateral	32	0
Central vision loss	2	0
Night blindness	4	0
Sudden visual loss	5	0
Visual acuity reduced	32	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021

Data Lock Date: 14-Jul-2021 18:30:32

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual acuity reduced transiently	1	0
Visual impairment	680	0
Visual pathway disorders		
Optic nerve disorder	2	0
Optic neuropathy	8	0
Eye disorders SOC TOTAL	13182	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	4	0
Gastrointestinal sounds abnormal	23	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	35	2
Pancreatitis acute	18	0
Pancreatitis chronic	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
<i>Anal and rectal pains</i>		
Proctalgia	26	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	9	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal spasm	2	0
Rectal tenesmus	2	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	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	3	0
Colitis	52	0
Colitis ischaemic	6	1
Colitis microscopic	5	0
Colitis ulcerative	94	0
Crohn's disease	84	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	2	0
Teething	21	0
Tooth disorder	4	0
Tooth socket haemorrhage	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	12	0
Dental paraesthesia	17	0
Hyperaesthesia teeth	58	0
Hypoaesthesia teeth	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Toothache	320	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	19	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	16	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	8592	0
Diarrhoea haemorrhagic	33	0
<i>Diverticula</i>		
Diverticulum	10	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
Superior mesenteric artery syndrome	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer	2	0
Duodenal ulcer haemorrhage	2	1
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	841	0
Epigastric discomfort	19	0
Eructation	98	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	20	0
Faecaloma	4	0
Faeces discoloured	49	0
Faeces hard	4	0
Faeces pale	6	0
Faeces soft	21	0
Mucous stools	14	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	610	0
Flatulence	386	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	12	1
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	13	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	4	0
Gastritis	93	0
Reflux gastritis	15	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	3	0
Abdominal pain	4381	0
Abdominal pain lower	239	0
Abdominal pain upper	5037	0
Abdominal rigidity	53	0
Abdominal tenderness	20	0
Gastrointestinal pain	308	0
Oesophageal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		

Case Series Drug Analysis Print

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Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Constipation	443	0
Duodenogastric reflux	2	0
Gastric dilatation	18	0
Gastrooesophageal reflux disease	219	0
Impaired gastric emptying	6	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	1	0
Food poisoning	12	0
Functional gastrointestinal disorder	12	0
Gastric disorder	9	0
Gastrointestinal disorder	35	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	5	0
Change of bowel habit	18	0
Defaecation disorder	1	0
Dyschezia	13	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	3	0
<i>Gastrointestinal fistulae</i>		
Anal fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Appendicitis noninfective	2	0
Enteritis	1	0
Gastrointestinal inflammation	1	0
Gastrointestinal tract irritation	4	0
Intestinal angioedema	1	0
Ischaemic enteritis	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Achlorhydria	1	0
Hyperchlorhydria	3	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1532	0
Abdominal symptom	5	0
Acute abdomen	17	0
Anal incontinence	46	0
Breath odour	24	0
Dysphagia	235	0
Intestinal congestion	1	0
Odynophagia	32	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	2	1
Defaecation urgency	15	0
Frequent bowel movements	46	0
Irritable bowel syndrome	131	0
Oesophageal spasm	6	0

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	4	0
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	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Gastrointestinal ischaemia	1	0
Intestinal infarction	6	1
Intestinal ischaemia	30	1
Mesenteric artery embolism	1	0
Mesenteric artery thrombosis	3	0
Mesenteric vein thrombosis	19	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	23	0
Gingival discomfort	6	0
Gingival disorder	13	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	227	0
Gingival pruritus	1	0
Gingival recession	2	0
Gingival swelling	48	0
Gingival ulceration	8	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	21	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	160	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoidal haemorrhage	4	0
Haemorrhoids	64	0
Haemorrhoids thrombosed	12	0
<i>Inguinal hernias</i>		
Inguinal hernia	3	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	40	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	4	0
Rectal haemorrhage	112	0
Small intestinal haemorrhage	27	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	4	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	1	0
Large intestinal stenosis	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	1	0
Coeliac disease	20	0
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Cyclic vomiting syndrome	1	0
Discoloured vomit	18	0
Faecal vomiting	3	0
Infantile spitting up	1	0
Infantile vomiting	3	0
Nausea	32654	0
Regurgitation	3	0
Retching	228	0
Vomiting	11033	1
Vomiting projectile	152	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	32	1
Haematemesis	76	0
Haematochezia	98	0
Intra-abdominal haematoma	1	0
Intra-abdominal haemorrhage	1	0
Melaena	9	0
Upper gastrointestinal haemorrhage	4	0
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	2	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal obstruction	1	0
<i>Oesophageal ulcers and perforation</i>		
Oesophageal ulcer	1	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	3	0
Oesophagitis	16	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	4	0
Dry mouth	1110	0
Lip dry	77	0
Saliva altered	6	0
Saliva discolouration	1	0
Salivary hypersecretion	81	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	4	0
Chapped lips	22	0
Cheilitis	36	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	36	0
Lip disorder	4	0

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Oral disorder	17	0
Oral lichen planus	12	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
Oral soft tissue haemorrhages		
Lip haemorrhage	4	0
Mouth haemorrhage	50	0
Oral blood blister	50	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	10	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	8	0
Burning mouth syndrome	14	0
Coating in mouth	4	0
Hypoaesthesia oral	619	0
Lip discolouration	1	0
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	60	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	94	0
Oral mucosal blistering	31	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	27	0
Oral mucosal erythema	4	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral pain	351	0
Oral pruritus	20	0
Paraesthesia oral	825	0
Oral soft tissue swelling and oedema		
Lip oedema	9	0
Lip swelling	924	0
Mouth swelling	119	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	14	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	5	0
Peritoneal and retroperitoneal disorders		
Ascites	6	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Retroperitoneal haemorrhage	1	0
Rectal inflammations NEC		
Proctitis	4	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
Salivary gland enlargement	5	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Aphthous ulcer	63	0
Lip ulceration	16	0
Mouth ulceration	731	0
Stomatitis	104	0
Tongue disorders		
Acquired macroglossia	1	0
Glossitis	17	0
Plicated tongue	4	0
Tongue disorder	29	0
Tongue geographic	5	0
Tongue haemorrhage	2	0
Tongue ulceration	32	0
Trichoglossia	7	0
Tongue signs and symptoms		
Glossodynia	252	0
Scalloped tongue	4	0
Stiff tongue	5	0
Strawberry tongue	1	0
Swollen tongue	590	0
Tongue blistering	28	0
Tongue coated	35	0
Tongue discolouration	37	0
Tongue discomfort	53	0
Tongue dry	21	0
Tongue eruption	10	0
Tongue erythema	6	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	17	0
Tongue pruritus	3	0
Tongue rough	2	0
Tongue spasm	3	0
Tooth missing		
Tooth loss	7	0
Gastrointestinal disorders SOC TOTAL	76836	13

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	17	0
Administration site coldness	1	0
Administration site erythema	6	0
Administration site extravasation	1	0
Administration site haemorrhage	1	0
Administration site induration	1	0
Administration site irritation	1	0
Administration site mass	1	0
Administration site movement impairment	1	0
Administration site pain	44	0
Administration site rash	4	0
Administration site reaction	5	0
Administration site swelling	3	0
Administration site urticaria	5	0
Administration site warmth	2	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	16	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	2	0
Application site discharge	1	0
Application site discolouration	2	0
Application site erythema	29	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 movement impairment	1	0
Application site odour	1	0
Application site pain	48	0
Application site pruritus	19	0
Application site rash	4	0
Application site reaction	1	0
Application site scar	1	0
Application site swelling	4	0
Application site vesicles	12	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

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Instillation site warmth	12	0
<i>Asthenic conditions</i>		
Asthenia	4693	3
Chronic fatigue syndrome	129	0
Decreased activity	11	0
Fatigue	48357	0
Malaise	12121	3
Sluggishness	28	0
<i>Body temperature altered</i>		
Hyperthermia	11	0
Hypothermia	54	0
Temperature regulation disorder	27	0
<i>Complications associated with device NEC</i>		
Complication of device removal	1	0
Injury associated with device	9	0
Medical device site joint pain	1	0
Phantom shocks	4	0
<i>Death and sudden death</i>		
Brain death	4	4
Death	286	285
Drowning	1	1
Sudden death	32	32
Sudden unexplained death in epilepsy	1	1
<i>Febrile disorders</i>		
Hyperpyrexia	42	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	54202	0
<i>Feelings and sensations NEC</i>		
Chills	42591	0
Early satiety	1	0
Feeling abnormal	3053	0
Feeling cold	5162	0
Feeling drunk	128	0
Feeling hot	2364	0
Feeling jittery	43	0
Feeling of body temperature change	938	0
Feeling of relaxation	1	0
Hangover	187	0
Hunger	81	0
Sensation of blood flow	13	0
Sensation of foreign body	50	0
Temperature intolerance	78	0
Thirst	1232	0
Thirst decreased	11	0
<i>Fibrosis NEC</i>		
Fibrosis	5	0
<i>Gait disturbances</i>		
Decreased gait velocity	3	0
Gait disturbance	400	0
Gait inability	189	0
Loss of control of legs	52	0
<i>General signs and symptoms NEC</i>		

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	244	0
Crepitations	7	0
Crying	277	0
Deformity	1	0
Developmental delay	7	0
Discharge	8	0
Disease progression	1	0
Disease recurrence	2	0
Effusion	1	0
Energy increased	26	0
Exercise tolerance decreased	35	0
Foaming at mouth	5	0
General physical health deterioration	24	1
General symptom	10	0
Glassy eyes	6	0
High-pitched crying	8	0
Ill-defined disorder	6	0
Illness	4892	0
Induration	21	0
Influenza like illness	9386	1
Irritability postvaccinal	3	0
Local reaction	155	0
Moaning	9	0
Multiple organ dysfunction syndrome	19	8
Nonspecific reaction	3	0
Organ failure	2	0
Perforation	3	0
Peripheral swelling	5593	1
Pre-existing condition improved	14	0
Premature ageing	1	0
Prolapse	1	0
Screaming	29	0
Secretion discharge	32	0
Sensitivity to weather change	2	0
Stenosis	2	0
Swelling	2609	0
Swelling face	1014	0
Symptom recurrence	4	0
Tissue discolouration	1	0
Tissue infiltration	1	0
Unevaluable event	14	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

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site pain	4	0
Implant site rash	1	0
Implant site swelling	3	0
Implant site urticaria	2	0
Implant site vesicles	1	0
Implant site warmth	7	0
Inflammations		
Granuloma	1	0
Inflammation	739	0
Papillitis	1	0
Systemic inflammatory response syndrome	5	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	13	0
Infusion site urticaria	2	0
Infusion site warmth	6	0
Injection site reactions		
Injected limb mobility decreased	41	0
Injection site atrophy	9	0
Injection site bruising	121	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	19	0
Injection site dryness	1	0
Injection site erythema	584	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	3	0
Injection site haemorrhage	17	0
Injection site hypersensitivity	5	0
Injection site hypoaesthesia	15	0
Injection site indentation	17	0
Injection site induration	9	0
Injection site inflammation	62	0
Injection site injury	5	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	1394	0
Injection site movement impairment	5	0
Injection site muscle weakness	1	0
Injection site necrosis	6	0
Injection site nerve damage	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site nodule	4	0
Injection site oedema	27	0
Injection site pain	4417	0
Injection site papule	2	0
Injection site paraesthesia	25	0
Injection site pruritus	291	0
Injection site rash	304	0
Injection site reaction	120	0
Injection site scab	4	0
Injection site scar	6	0
Injection site swelling	254	0
Injection site thrombosis	1	0
Injection site ulcer	1	0
Injection site urticaria	38	0
Injection site vesicles	14	0
Injection site warmth	351	0
Interactions		
Drug interaction	32	0
Food interaction	2	0
Inhibitory drug interaction	12	0
Mass conditions NEC		
Cyst	25	0
Mass	84	0
Nodule	20	0
Mucosal findings abnormal		
Mucosa vesicle	2	0
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	8	0
Mucosal inflammation	9	0
Mucosal pain	2	0
Mucosal ulceration	1	0
Oedema mucosal	3	0
Polyp	4	0
Necrosis NEC		
Fat necrosis	2	0
Necrosis	8	0
Oedema NEC		
Face oedema	33	0
Localised oedema	11	0
Oedema	76	0
Oedema peripheral	143	0
Pain and discomfort NEC		
Axillary pain	728	0
Chest discomfort	1965	0
Chest pain	5046	2
Discomfort	561	0
Facial discomfort	21	0
Facial pain	266	0
Hernia pain	2	0
Inflammatory pain	24	0
Non-cardiac chest pain	41	0
Pain	16327	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Suprapubic pain	1	0
Tenderness	1802	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	111	0
Adverse event	41	0
Adverse reaction	61	0
Diet failure	1	0
Drug ineffective	167	1
Drug intolerance	7	0
Idiosyncratic drug reaction	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	28	0
No reaction on previous exposure to drug	84	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	5	0
Therapeutic reaction time decreased	1	0
Therapeutic response decreased	1	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	163	0
Therapy non-responder	3	0
Treatment failure	10	0
Treatment noncompliance	1	0
Vaccination failure	35	0
Vaccine positive rechallenge	1	0
Trophic disorders		
Atrophy	4	0
Calcinosis	2	0
Dysplasia	3	0
Hyperplasia	1	0
Ulcers NEC		
Ulcer	44	0
Ulcer haemorrhage	4	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	19	0
Shoulder injury related to vaccine administration	51	0
Vaccination site atrophy	1	0
Vaccination site bruising	134	0
Vaccination site coldness	1	0
Vaccination site cyst	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	15	0
Vaccination site discomfort	47	0
Vaccination site dryness	1	0
Vaccination site erythema	688	0
Vaccination site extravasation	1	0
Vaccination site granuloma	8	0
Vaccination site haematoma	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site haemorrhage	8	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	4	0
Vaccination site hypoaesthesia	25	0
Vaccination site induration	66	0
Vaccination site inflammation	51	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	542	0
Vaccination site movement impairment	80	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	2003	0
Vaccination site papule	3	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	104	0
Vaccination site rash	186	0
Vaccination site reaction	26	0
Vaccination site scab	2	0
Vaccination site scar	7	0
Vaccination site swelling	489	0
Vaccination site urticaria	11	0
Vaccination site vesicles	10	0
Vaccination site warmth	373	0
<i>Vascular complications associated with device</i>		
Vascular stent occlusion	1	0
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	91	0
General disorders SOC TOTAL	243745	343

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	29	0
Cholangitis	4	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	14	0
Cholecystitis acute	1	0
Cholelithiasis	14	0
<i>Cholestasis and jaundice</i>		
Cholestasis	5	0
Jaundice	50	0
Jaundice cholestatic	11	0
Ocular icterus	1	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	2	0
Gallbladder oedema	1	0
Gallbladder polyp	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	15	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	8	0
Subacute hepatic failure	3	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	7	0
<i>Hepatic vascular disorders</i>		
Budd-Chiari syndrome	2	1
Hepatic artery thrombosis	1	0
Hepatic haemorrhage	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	0
Hepatic vein thrombosis	15	0
Portal hypertension	2	0
Portal vein phlebitis	1	0
Portal vein thrombosis	59	5
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	66	0
Hepatomegaly	4	0
Liver tenderness	6	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	5	0
Drug-induced liver injury	2	0
Hepatic necrosis	1	0
Hepatic steatosis	8	0
Hepatitis	26	0
Hepatitis acute	7	1
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0
Liver injury	20	0
Reye's syndrome	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021

Data Lock Date: 14-Jul-2021 18:30:32

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders Hepatic disorders cont'd		
Biliary obstruction	1	0
Sphincter of Oddi dysfunction	3	0
Hepatic disorders SOC TOTAL	415	8

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
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	4	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	2	0
Hypersensitivity	1385	0
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	16	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	6	0
Type IV hypersensitivity reaction	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	3	0
Allergy to chemicals	7	0
Allergy to vaccine	57	0
Contrast media reaction	4	0
Drug hypersensitivity	62	0
Food allergy	34	0
Oral allergy syndrome	4	0
Reaction to colouring	1	0
Reaction to excipient	14	0
Reaction to preservatives	15	0
Rubber sensitivity	1	0
Smoke sensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	646	2
Anaphylactic shock	113	0
Anaphylactoid reaction	23	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	121	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	45	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	34	0
Cytokine release syndrome	2	0
Cytokine storm	4	0
Haemophagocytic lymphohistiocytosis	12	0
Immune system disorder	33	0
Immune-mediated adverse reaction	9	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
 Earliest Reaction Date: 03-Feb-1921

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Immunisation reaction	1	0
Multiple chemical sensitivity	1	0
Pre-engraftment immune reaction	1	0
Sensitisation	32	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	7	0
Immunosuppression	3	0
<i>Transplant rejections</i>		
Corneal graft rejection	3	0
Transplant rejection	7	0
<i>Vasculitides</i>		
Anti-neutrophil cytoplasmic antibody positive vasculitis	1	0
Eosinophilic granulomatosis with polyangiitis	1	0
Immune system disorders SOC TOTAL	2813	2

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
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Data Lock Date: 14-Jul-2021 18:30:32
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	34	0
Appendicitis perforated	3	0
Diarrhoea infectious	4	0
Diverticulitis	27	0
Dysentery	5	0
Gastric infection	1	0
Gastroenteritis	39	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	8	0
Bacterial infection	32	1
Bacterial vaginosis	3	0
Cellulitis	507	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
Meningitis bacterial	1	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>		
Breast abscess	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Mastitis	42	0
<i>Brucella infections</i>		
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	76	0
Oral candidiasis	54	0
Skin candida	2	0
Vulvovaginal candidiasis	57	0
<i>Cardiac infections</i>		
Endocarditis	4	0
Myocarditis infectious	1	0
<i>Central nervous system and spinal infections</i>		
Cavernous sinus thrombosis	9	0
Central nervous system infection	1	0
Encephalitis	37	0
Encephalomyelitis	3	0
Extradural abscess	1	0
Meningitis	27	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	569	22
COVID-19 pneumonia	35	9
Coronavirus infection	5	0
Post-acute COVID-19 syndrome	5	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	40	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	8	0
Gingivitis	29	0
Lip infection	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Oral infection	1	0
Oral pustule	3	0
Parotitis	13	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tongue abscess	4	0
Tooth abscess	16	0
Tooth infection	13	0
Ear infections		
Ear infection	130	0
Labyrinthitis	164	0
Mastoiditis	4	0
Otitis externa	7	0
Otitis media	20	0
Otosalpingitis	1	0
Ectoparasitic infestations		
Acarodermatitis	8	0
Infestation	1	0
Trombidiasis	3	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	2	0
Infectious mononucleosis	52	0
Escherichia infections		
Escherichia infection	2	0
Escherichia sepsis	2	0
Eye and eyelid infections		
Conjunctivitis	82	0
Eye infection	36	0
Eyelid boil	3	0
Eyelid infection	4	0
Hordeolum	36	0
Keratouveitis	1	0
Retinitis	2	0
Female reproductive tract infections		
Endometritis	2	0
Fallopian tube abscess	1	0
Ovarian abscess	1	0
Pelvic inflammatory disease	1	0
Pyometra	1	1
Vaginal abscess	3	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	22	0
Fungal skin infection	10	0
Oral fungal infection	1	0
Overgrowth fungal	1	0
Severe asthma with fungal sensitisation	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	4	0
Hepatitis virus infections		
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	5	1
Splenic infection	1	0
Herpes viral infections		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	3	0
Genital herpes	63	0
Genital herpes simplex	1	0
Haemorrhagic varicella syndrome	1	0
Herpes dermatitis	2	0
Herpes ophthalmic	15	0
Herpes pharyngitis	1	0
Herpes simplex	40	0
Herpes simplex reactivation	4	0
Herpes virus infection	14	0
Herpes zoster	1457	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	10	0
Oral herpes	674	0
Varicella	35	0
Varicella zoster virus infection	3	0
Infections NEC		
Abscess	46	0
Abscess limb	22	0
Abscess soft tissue	2	0
Catheter site infection	1	0
Coinfection	1	0
Device related infection	3	0
Genital abscess	1	0
Groin abscess	1	0
Groin infection	1	0
Infected bite	4	0
Infected cyst	4	0
Infection	485	3
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	20	0
Localised infection	104	0
Lymph gland infection	6	0
Lymph node abscess	2	0
Omphalitis	1	0
Pathogen resistance	3	0
Pelvic infection	1	0
Pyuria	1	0

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Respiratory tract infection	6	0
Toxic shock syndrome	1	0
Vaccination site abscess	5	0
Vaccination site infection	23	0
Vestibulitis	3	0
Wound abscess	1	0
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	1	0
<i>Infectious transmissions</i>		
Secondary transmission	16	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
H2N2 influenza	3	0
Influenza	6664	0
<i>Klebsiella infections</i>		
Pneumonia klebsiella	1	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	2	0
Bronchitis	23	0
Infectious pleural effusion	4	0
Infective exacerbation of bronchiectasis	1	0
Infective pulmonary exacerbation of cystic fibrosis	1	1
Lower respiratory tract infection	278	4
Pleural infection	1	0
Pneumonia	227	22
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	6	0
Orchitis	4	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	11	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	2	0
Soft tissue infection	5	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Orthopox viral infections</i>		
Cow pox	1	0
<i>Papilloma viral infections</i>		
Papilloma viral infection	1	0
<i>Paravaccinia infections</i>		
Paravaccinia	1	0
<i>Phleboviral infections</i>		
Severe fever with thrombocytopenia syndrome	2	0
<i>Plasmodia infections</i>		
Malaria	6	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	2	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	2	0
HIV infection	1	0
HIV-associated neurocognitive disorder	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
Rotavirus infection	1	0
<i>Rubella viral infections</i>		
Rubella	1	0
<i>Rubeola viral infections</i>		
Measles	5	0
<i>Salmonella infections</i>		
Typhoid fever	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Abdominal sepsis	1	0
Bacteraemia	1	0
Neutropenic sepsis	8	0
Sepsis	99	12
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	11	0
Septic shock	4	1
Urosepsis	9	1
Viraemia	4	0
<i>Skin structures and soft tissue infections</i>		
Blister infected	1	0
Carbuncle	1	0
Dermatitis infected	10	0
Eczema infected	3	0
Impetigo	9	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	23	0
Rash pustular	19	0
Skin infection	67	0
Subcutaneous abscess	10	0
Vaccination site pustule	5	0
<i>Staphylococcal infections</i>		
Furuncle	51	0
Staphylococcal bacteraemia	2	0
Staphylococcal infection	1	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	3	1
Toxic shock syndrome staphylococcal	2	0
Vulvovaginitis staphylococcal	1	0
<i>Streptococcal infections</i>		
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

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Tinea infections</i>		
Body tinea	7	0
Tinea cruris	1	0
Tinea infection	1	0
Tinea pedis	4	0
Tinea versicolour	1	0
<i>Treponema infections</i>		
Neurosyphilis	1	0
Syphilis	3	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	6	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Erythema induratum	1	0
Lymph node tuberculosis	3	0
Meningitis tuberculous	1	0
Pulmonary tuberculosis	2	0
Tuberculosis	4	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	5	0
Chronic sinusitis	14	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	33	0
Nasal vestibulitis	1	0
Nasopharyngitis	1808	0
Pharyngeal abscess	1	0
Pharyngitis	36	0
Rhinitis	50	0
Sinobronchitis	1	0
Sinusitis	350	0
Tonsillitis	77	0
Tracheitis	1	0
Upper respiratory tract infection	10	0
<i>Urinary tract infections</i>		
Cystitis	91	0
Genitourinary tract infection	1	0
Kidney infection	56	0
Pyelonephritis	5	0
Pyelonephritis acute	1	0
Pyelonephritis chronic	1	0
Renal abscess	2	0
Urethritis	1	0
Urinary tract infection	232	0
<i>Vascular infections</i>		
Haematoma infection	2	0
Infected lymphocele	1	0
Infected varicose vein	1	0
Lymphangitis	6	0
<i>Viral infections NEC</i>		
Arthritis viral	2	0
Bronchitis viral	1	0
Ear infection viral	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021

Data Lock Date: 14-Jul-2021 18:30:32

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Encephalitis viral	7	0
Eye infection viral	1	0
Gastritis viral	1	0
Gastroenteritis viral	67	0
Gastrointestinal viral infection	1	0
Hepatitis viral	2	0
Meningitis viral	18	0
Pleurisy viral	1	0
Pneumonia viral	8	1
Post viral fatigue syndrome	116	0
Sweating fever	729	0
Vestibular neuronitis	33	0
Viral diarrhoea	4	0
Viral infection	81	0
Viral labyrinthitis	7	0
Viral myocarditis	1	0
Viral pericarditis	4	0
Viral pharyngitis	31	0
Viral rash	79	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	17408	84

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
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	2	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	17	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	10	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	5	0
Vascular injury	8	0
Venous injury	1	0
<i>Cerebral injuries NEC</i>		
Brain contusion	13	0
Brain herniation	4	0
Concussion	7	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	1	0
Subarachnoid haematoma	2	0
Subdural haematoma	7	1
Subdural haemorrhage	5	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

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Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Chemical phlebitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	12	0
Chest injury	1	0
Foreign body in throat	1	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	70	0
Frostbite	1	0
<i>Cranial nerve injuries</i>		
Cranial nerve injury	1	0
Optic nerve injury	4	0
Vth nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	15	0
Exposure via breast milk	75	0
Foetal exposure during pregnancy	48	0
Maternal exposure before pregnancy	4	0
Maternal exposure during breast feeding	1286	0
Maternal exposure during pregnancy	297	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	7	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	4	0
Exposure to household chemicals	1	0
Exposure to toxic agent	1	0
Exposure to vaccinated person	2	0
<i>Eye injuries NEC</i>		
Cataract traumatic	1	0
Eye contusion	51	0
Eye injury	36	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
<i>Foetal and neonatal conditions associated with product exposure</i>		
Intoxication by breast feeding	1	0
<i>Fractures and dislocations NEC</i>		
Fracture	1	0
Joint dislocation	10	0
Multiple fractures	2	0
Stress fracture	4	0
Traumatic fracture	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Peripancreatic fluid collection	1	0
Procedural nausea	26	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Procedural vomiting	7	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
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 dose omission	5	0
Intentional product use issue	1	0
Limb fractures and dislocations		
Ankle fracture	3	0
Atypical femur fracture	1	0
Clavicle fracture	20	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	8	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	87	0
Prescription drug used without a prescription	2	0
Product use issue	6	0
Vaccination error	9	0
Wrong device used	1	0
Wrong drug	5	0
Wrong route	1	0
Wrong schedule	2	0
Wrong technique in product usage process	7	0
Muscle, tendon and ligament injuries		
Epicondylitis	24	0
Ligament injury	3	0
Ligament rupture	2	0
Ligament sprain	18	0
Muscle injury	47	0
Muscle rupture	18	0
Muscle strain	47	0
Post-traumatic neck syndrome	3	0
Repetitive strain injury	3	0
Tendon injury	4	0
Tendon rupture	16	0

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Nerve injuries NEC</i>		
Nerve injury	118	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	8	0
Procedural dizziness	33	0
<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	6	0
Arthropod sting	12	0
Bite	1	0
Child maltreatment syndrome	1	0
Electric shock	32	0
Fall	244	0
Foreign body	1	0
Inflammation of wound	4	0
Injury	14	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	4	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	1	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
Post procedural haemorrhage	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

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Off label uses		
Off label use	30	0
Overdoses NEC		
Intentional overdose	11	0
Overdose	30	0
Prescribed overdose	1	0
Pathways and sources of exposure		
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
Radial nerve injury	1	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	6	0
Systemic toxicity	1	0
Toxicity to various agents	11	0
Product administration errors and issues		
Accidental overdose	4	0
Accidental underdose	2	0
Contraindicated product administered	4	0
Drug administered in wrong device	1	0
Duplicate therapy error	2	0
Expired product administered	27	0
Extra dose administered	7	0
Inappropriate schedule of product administration	47	0
Incomplete course of vaccination	4	0
Incorrect dose administered	11	0
Incorrect product administration duration	2	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	41	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	18	0
Product administered to patient of inappropriate age	26	0
Product administration error	24	0
Product dose omission issue	10	0
Wrong patient received product	1	0
Wrong product administered	19	0
Product confusion errors and issues		
Product label confusion	1	0
Product name confusion	2	0
Product dispensing errors and issues		
Product dispensing error	15	0
Product monitoring errors and issues		
Documented hypersensitivity to administered product	1	0
Labelled drug-drug interaction medication error	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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	7	0
Product transcribing errors and communication issues		
Product communication issue	1	0
Radiation injuries		
Sunburn	52	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	6	0
Central nervous system injury	1	0
Face crushing	1	0
Face injury	3	0
Head injury	39	0
Limb crushing injury	9	0
Limb injury	249	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	3046	0
Hair injury	1	0
Nail injury	1	0
Scar	31	0
Scratch	5	0
Skin abrasion	5	0
Skin injury	19	0
Skin laceration	2	0
Skin pressure mark	1	0
Skin wound	6	0
Subcutaneous haematoma	3	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Spinal cord injuries NEC		

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury	2	0
Spinal cord injury sacral	1	0
<i>Spinal fractures and dislocations</i>		
Spinal compression fracture	3	0
Spinal fracture	7	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
Stoma site haemorrhage	1	0
Stoma site pain	2	0
Stoma site rash	1	0
<i>Thermal burns</i>		
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	49	0
Thermal burns of eye	46	0
<i>Thoracic cage fractures and dislocations</i>		
Rib fracture	1	0
<i>Transplantation complications</i>		
Transplant failure	1	0
<i>Underdoses NEC</i>		
Intentional underdose	1	0
Underdose	10	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	5	0
Post vaccination syndrome	1	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	95	0
Injuries SOC TOTAL	7944	1

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Blood cortisol	1	0
Cortisol decreased	2	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	8	0
Audiogram	1	0
<i>Autoimmunity analyses</i>		
Antimitochondrial antibody positive	1	0
Antineutrophil cytoplasmic antibody	1	0
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody positive	1	0
Antiphospholipid antibodies	2	0
Antiphospholipid antibodies positive	3	0
Cold agglutinins positive	1	0
DNA antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	4	0
Smooth muscle antibody	1	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	11	0
Blood count abnormal	6	0
Full blood count	7	0
Full blood count abnormal	3	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	3	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	182	1
Oxygen saturation normal	1	0
<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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood glucose abnormal	18	0
Blood glucose decreased	39	0
Blood glucose fluctuation	33	0
Blood glucose increased	183	0
Glycosylated haemoglobin increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur	28	0
Heart sounds	17	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	18	0
Stroke volume decreased	2	0
Venous pressure jugular increased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Cell marker analyses		
Carbohydrate antigen 15-3	1	0
Carcinoembryonic antigen increased	2	0
Prostatic specific antigen decreased	1	0
Prostatic specific antigen increased	2	0
Tumour marker increased	1	0
Central nervous system histopathology procedures		
Biopsy brain	1	0
Central nervous system imaging procedures		
Brain scan abnormal	1	0
Computerised tomogram head	23	0
Magnetic resonance imaging head	44	0
Magnetic resonance imaging head normal	1	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
Serum serotonin increased	1	0
Cholesterol analyses		
Blood cholesterol increased	12	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	127	0
Anti factor VIII antibody positive	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Bleeding time	9	0
Bleeding time abnormal	3	0
Bleeding time prolonged	6	0
Bleeding time shortened	1	0
Blood fibrinogen decreased	7	0
Blood fibrinogen increased	2	0
Blood thromboplastin	1	0
Blood thromboplastin abnormal	1	0
Blood thromboplastin increased	1	0
Clot retraction	1	0
Coagulation factor	1	0
Coagulation factor VIII level decreased	4	0
Coagulation time	9	0
Coagulation time prolonged	14	0
Coagulation time shortened	4	0
Fibrin D dimer	1	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	50	0
International normalised ratio	2	0
International normalised ratio abnormal	11	0
International normalised ratio decreased	41	0
International normalised ratio fluctuation	5	0
International normalised ratio increased	86	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	7	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	2	0
Electrocardiogram ST-T segment abnormal	6	0
Electrocardiogram T wave inversion	4	0
Electrocardiogram abnormal	18	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	45	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 analysis abnormal	1	0
Semen volume decreased	2	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Computerised tomogram abdomen	4	0
Stomach scan	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastric pH	1	0
Gastric pH decreased	2	0
Gastrointestinal stoma output increased	1	0
Swallow study	3	0
<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	3	0
Haematology test abnormal	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate	1	0
Red blood cell sedimentation rate abnormal	1	0
Red blood cell sedimentation rate increased	7	0
<i>Heart rate and pulse investigations</i>		
Brachial pulse decreased	1	0
Carotid pulse	1	0
Femoral pulse	1	0
Heart rate	1048	0
Heart rate abnormal	54	0
Heart rate decreased	116	0
Heart rate increased	1991	0
Heart rate irregular	194	0
Heart rate variability decreased	1	0
Heart rate variability increased	2	0
Maximum heart rate	6	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Popliteal pulse	1	0
Pulse abnormal	30	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Magnetic resonance imaging abnormal	1	0
Magnetic resonance imaging whole body	1	0
Scan	1	0
X-ray	1	0
Immunoglobulin analyses		
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
Immunology analyses NEC		
Antibody test	3	0
Antibody test abnormal	1	0
Antibody test negative	7	0
Immunology test	10	0
Immunology test normal	1	0
Mast cell degranulation present	1	0
Tryptase increased	1	0
Immunology skin tests NEC		
Allergy alert test	2	0
Skin test positive	5	0
Investigations NEC		
APACHE II score	1	0
Blood test	46	0
Blood test abnormal	68	0
Laboratory test	1	0
Polymerase chain reaction positive	2	0
Quality of life decreased	3	0
Liver function analyses		
Alanine aminotransferase increased	25	0
Aspartate aminotransferase increased	3	0
Bile output	4	0
Blood bilirubin	1	0
Blood bilirubin increased	3	0
Gamma-glutamyltransferase increased	3	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	14	0
Liver function test	3	0
Liver function test abnormal	45	0
Liver function test increased	11	0
Transaminases increased	10	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

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood calcium increased	1	0
Blood cyanide	1	0
Blood iron	10	0
Blood iron decreased	20	0
Blood iron increased	2	0
Blood magnesium decreased	3	0
Blood phosphorus abnormal	1	0
Blood phosphorus decreased	6	0
Blood phosphorus increased	3	0
Blood potassium decreased	11	0
Blood potassium increased	9	0
Blood sodium	2	0
Blood sodium decreased	5	0
Blood zinc increased	1	0
Serum ferritin	1	0
Serum ferritin decreased	2	0
Serum ferritin increased	4	0
Sweat test	3	0
Urine copper	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone densitometry	1	0
Skull X-ray	10	0
X-ray limb	1	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	4	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	19	0
Electromyogram abnormal	3	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	16	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
Retinal function test abnormal	1	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	1023	0
Body temperature abnormal	85	0
Body temperature decreased	134	0
Body temperature fluctuation	178	0
Body temperature increased	1118	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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
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	26	0
Respiratory rate increased	77	0
Skin temperature	176	0
Temperature difference of extremities	7	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	180	0
Weight increased	44	0
<i>Pituitary analyses anterior</i>		
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
<i>Platelet analyses</i>		
Platelet count	2	0
Platelet count abnormal	2	0
Platelet count decreased	292	0
Platelet count increased	6	0
Platelet count normal	1	0
Plateletcrit	1	0
<i>Protein analyses NEC</i>		
C-reactive protein	1	0
C-reactive protein abnormal	3	0
C-reactive protein increased	25	0
Protein total	2	0
Protein total increased	1	0
<i>Red blood cell analyses</i>		
Haematocrit	9	0
Haematocrit decreased	1	0
Haematocrit increased	3	0
Haemoglobin	7	0
Haemoglobin decreased	15	0

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Haemoglobin increased	1	0
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	2	0
Red blood cell count	3	0
Red blood cell count decreased	2	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	7	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	3	0
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
Oestradiol	1	0
Pregnancy test	17	0
Pregnancy test false positive	2	0
Pregnancy test negative	2	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	1	0
Biopsy vagina	1	0
Smear cervix	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	13	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	5	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	18	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Ventilation/perfusion scan	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	7	0
Muscle enzyme increased	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	1	0
Troponin	2	0
Troponin I increased	2	0
Troponin T	1	0
Troponin T increased	1	0
<i>Special sense investigations NEC</i>		
Olfactory test	1	0
<i>Therapeutic drug monitoring analyses</i>		
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
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	3	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>Triglyceride analyses</i>		
Blood triglycerides	1	0
<i>Urinalysis NEC</i>		
Blood urine	36	0
Blood urine present	82	0
Cells in urine	2	0
Crystal urine	4	0
Glucose urine	1	0
Haemoglobin urine	1	0
Medication crystals in urine present	1	0
Protein urine	2	0
Protein urine present	1	0
Red blood cells urine	1	0

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Urea urine increased	1	0
Urine analysis	1	0
Urine analysis abnormal	13	0
Urine analysis normal	2	0
White blood cells urine positive	1	0
pH urine	9	0
pH urine decreased	2	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	46	0
Urine output decreased	18	0
Urine output increased	10	0
Urinary tract imaging procedures		
Cystoscopy	3	0
Ultrasound kidney	1	0
Vascular auscultatory investigations		
Abdominal bruit	1	0
Carotid bruit	1	0
Vascular imaging procedures NEC		
Arteriogram carotid	1	0
Venogram	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	7	0
Blood pressure decreased	87	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure increased	298	0
Blood pressure measurement	103	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
Virus identification and serology		
Blood HIV RNA increased	1	0
Coronavirus test	38	0
Cytomegalovirus test	1	0
HIV antibody negative	2	0
Hepatitis B core antibody positive	1	0
Hepatitis B surface 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 RNA	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	24	0
SARS-CoV-2 antibody test positive	4	0
SARS-CoV-2 test	25	0
SARS-CoV-2 test false negative	5	0
SARS-CoV-2 test false positive	3	0
SARS-CoV-2 test negative	16	0
SARS-CoV-2 test positive	93	0
Viral test	4	0

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Viral test positive	1	0
Vitamin analyses		
Blood folate	2	0
Blood folate decreased	6	0
Vitamin B12	2	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	3	0
Vitamin D	3	0
Vitamin D decreased	4	0
Vitamin D increased	1	0
Water and electrolyte analyses NEC		
Blood electrolytes decreased	2	0
Blood osmolarity	1	0
Volume blood	7	0
White blood cell analyses		
CD4 lymphocytes decreased	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	5	0
Lymphocyte count	2	0
Lymphocyte count decreased	4	0
Lymphocyte count increased	3	0
Mononuclear cell count abnormal	1	0
Neutrophil count	3	0
Neutrophil count decreased	18	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	20	0
White blood cell count decreased	32	0
White blood cell count increased	10	0
Investigations SOC TOTAL	10184	1

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	37	0
Decreased appetite	6325	0
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	22	0
Food refusal	39	0
Hyperphagia	7	0
Hypophagia	33	0
Increased appetite	58	0
Salt craving	4	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	2	0
Hypocalcaemia	8	0
Tetany	1	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	94	0
Diabetes mellitus inadequate control	28	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	22	0
Type 2 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	35	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	167	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	10	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	12	0
Dairy intolerance	1	0
Food intolerance	15	0
Gluten sensitivity	4	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	59	0
Abnormal weight gain	28	0
Cachexia	2	0
Feeding disorder	194	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Food aversion	55	0
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0
Overfeeding of infant	1	0
Overweight	2	0
Poor feeding infant	17	0
Starvation	1	0
Underweight	2	0
Weight loss poor	3	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	99	0
Hypoglycaemia unawareness	3	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	13	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)		
Hyperlactacidaemia	1	0
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	5	0
Phosphorus metabolism disorders		
Hypophosphataemia	2	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	4	0
Hypokalaemic syndrome	2	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	2	0
Hyponatraemia	24	0
Hyponatraemic syndrome	4	1
Sugar intolerance (excl glucose intolerance)		

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Lactose intolerance	6	0
Total fluid volume decreased		
Dehydration	650	0
Hypovolaemia	2	0
Total fluid volume increased		
Fluid overload	7	0
Fluid retention	77	1
Vitamin deficiencies NEC		
Hypovitaminosis	2	0
Water soluble vitamin deficiencies		
Folate deficiency	7	0
Vitamin B12 deficiency	8	0
Metabolic disorders SOC TOTAL	8428	4

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	464	0
Arthritis enteropathic	1	0
Arthropathy	35	0
Autoimmune arthritis	10	0
Haemarthrosis	7	0
Oligoarthritis	1	0
Palindromic rheumatism	5	0
Polyarthritis	15	0
Rheumatic fever	5	0
Sacroiliitis	4	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	10	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1027	0
Bone swelling	6	0
Coccydynia	7	0
Pain in jaw	586	0
Pubic pain	1	0
Spinal pain	247	0
<i>Bursal disorders</i>		
Bursitis	149	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	71	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	2	0
Polymyalgia rheumatica	73	0
Reynold's syndrome	6	0
Scleroderma	4	0
Sjogren's syndrome	2	0
Systemic scleroderma	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Foot deformity	3	0
Hand deformity	3	0
Knee deformity	1	0
Limb deformity	8	0
Wrist deformity	2	0
Fractures NEC		
Osteoporotic fracture	3	0
Pathological fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc degeneration	2	0
Intervertebral disc protrusion	8	0
Joint related disorders NEC		
Ankle impingement	2	0
Femoroacetabular impingement	2	0
Hypermobility syndrome	2	0
Joint ankylosis	2	0
Joint contracture	1	0
Joint instability	2	0
Joint laxity	5	0
Joint lock	47	0
Ligament laxity	1	0
Patellofemoral pain syndrome	6	0
Periarthritis	328	0
Rotator cuff syndrome	65	0
Temporomandibular joint syndrome	19	0
Joint related signs and symptoms		
Arthralgia	21954	0
Jaw clicking	5	0
Joint effusion	9	0
Joint noise	49	0
Joint range of motion decreased	5	0
Joint stiffness	422	0
Joint swelling	910	0
Joint vibration	5	0
Joint warmth	34	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	41	0
Myositis ossificans	1	0
Polymyositis	2	0
Muscle pains		
Fibromyalgia	261	0
Myalgia	26047	0
Myalgia intercostal	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myofascial pain syndrome	24	0
Muscle related signs and symptoms NEC		
Haematoma muscle	3	0
Muscle atrophy	27	0
Muscle discomfort	19	0
Muscle disorder	10	0
Muscle fatigue	961	0
Muscle haemorrhage	3	0
Muscle hypertrophy	1	0
Muscle mass	12	0
Muscle oedema	2	0
Muscle spasms	3145	0
Muscle swelling	30	0
Muscle tightness	185	0
Muscle twitching	515	0
Muscle tone abnormalities		
Muscle rigidity	52	0
Nuchal rigidity	16	0
Torticollis	11	0
Trismus	53	0
Muscle weakness conditions		
Muscular weakness	1954	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	1	0
Extremity contracture	2	0
Infantile back arching	1	0
Limb mass	15	0
Mandibular mass	1	0
Mastication disorder	6	0
Mobility decreased	126	0
Muscle contracture	2	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	2193	0
Posture abnormal	2	0
Somatic dysfunction	1	0
Weight bearing difficulty	6	0
Winged scapula	1	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	3	0
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	11	0
Musculoskeletal and connective tissue pain and discomfort		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5584	0
Flank pain	75	0
Growing pains	8	0
Limb discomfort	2216	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal chest pain	401	0
Musculoskeletal discomfort	137	0
Musculoskeletal pain	68	0
Neck pain	2945	0
Pain in extremity	20944	0
Rheumatic disorder	23	0
Myopathies		
Compartment syndrome	4	0
Muscle necrosis	1	0
Myopathy	4	0
Rhabdomyolysis	9	1
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	70	0
Spinal osteoarthritis	5	0
Psoriatic arthropathies		
Psoriatic arthropathy	27	0
Rheumatoid arthropathies		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	164	0
Rheumatoid nodule	1	0
Still's disease	6	0
Soft tissue disorders NEC		
Axillary mass	76	0
Clubbing	1	0
Fistula	3	0
Groin pain	209	0
Neck mass	23	0
Soft tissue disorder	2	0
Soft tissue mass	3	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	5	0
Scoliosis	3	0
Spinal stenosis	2	0
Spondyloarthropathies		
Ankylosing spondylitis	29	0
Arthritis reactive	48	0
Axial spondyloarthritis	2	0
Spondylitis	4	0
Synovial disorders		
Synovial cyst	8	0
Synovitis	15	0
Tendon disorders		
Enthesopathy	1	0
Tendon discomfort	4	0
Tendon disorder	7	0
Tendon pain	35	0
Tendon sheath disorder	1	0
Tendonitis	77	0
Tenosynovitis	2	0
Tenosynovitis stenosans	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders cont'd		
Trigger finger	29	0
Muscle & tissue disorders SOC TOTAL	95796	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	2	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	48	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 benign</i>		
Cervix warts	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	3	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	3	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	6	0
<i>Glial tumours malignant</i>		
Glioblastoma	3	0
Glioblastoma multiforme	1	0
<i>Haematologic neoplasms NEC</i>		
Haematological malignancy	1	0
Systemic mastocytosis	1	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	3	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Hepatoblastomas		
Hepatoblastoma	1	0
Hodgkin's disease NEC		
Hodgkin's disease	2	0
Leiomyosarcomas		
Pleomorphic leiomyosarcoma	1	0
Leukaemias NEC		
Leukaemia	2	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	17	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	4	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	9	1
Squamous cell carcinoma	3	0
Neoplasms unspecified malignancy and site unspecified NEC		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Neoplasm recurrence	7	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	4	0
Meningioma	4	0
Schwannoma	1	0
<i>Neuromas</i>		
Acoustic neuroma	5	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Cutaneous lymphoma	1	0
Non-Hodgkin's lymphoma	1	0
<i>Non-small cell neoplasms malignant of the respiratory tract cell type specified</i>		
Lung adenocarcinoma	1	1
<i>Ocular neoplasms benign</i>		
Eye naevus	3	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	7	0
Oesophageal carcinoma	4	0
Oesophageal squamous cell carcinoma	1	0
<i>Oncologic complications and emergencies</i>		
Cancer fatigue	4	0
Cancer pain	2	0
Intracranial tumour haemorrhage	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	3	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	9	0
Ovarian cancer recurrent	1	0
Ovarian cancer stage IV	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	5	0
Pancreatic carcinoma metastatic	1	0
<i>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</i>		
Nasal cavity cancer	1	0
<i>Paraneoplastic syndromes NEC</i>		
Paraneoplastic syndrome	1	0
<i>Penile neoplasms malignant</i>		
Penile cancer	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	3	0
Plasmacytoma	1	0
<i>Plasma cell neoplasms NEC</i>		
Hypergammaglobulinaemia benign monoclonal	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	6	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	2	0
Metastatic renal cell carcinoma	1	0
Renal cancer	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Respiratory tract and pleural neoplasms malignancy unspecified NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Maxillofacial sinus neoplasm	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified</i>		
<i>NEC</i>		
Bronchial carcinoma	5	0
Lung cancer metastatic	1	0
Lung neoplasm malignant	11	0
Throat cancer	1	0
<i>Salivary gland neoplasms malignant</i>		
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
<i>Skin melanomas (excl ocular)</i>		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	2	0
Malignant melanoma in situ	1	0
Metastatic malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	5	0
Anogenital warts	2	0
Haemangioma of skin	16	0
Melanocytic naevus	4	0
Seborrhoeic keratosis	1	0
Skin papilloma	23	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	7	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Knuckle pads	1	0
Lipoma	6	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	8	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	2	0
<i>Vulval neoplasms malignant</i>		
Vulval cancer	1	0
Neoplasms SOC TOTAL	373	4

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	30	0
Extensor plantar response	2	0
Hyperreflexia	5	0
Hyporeflexia	17	0
Poor sucking reflex	4	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	24	0
<i>Absence seizures</i>		
Petit mal epilepsy	35	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	4	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	358	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	16	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	5	0
Cerebellar stroke	9	0
Cerebral artery embolism	9	0
Cerebral artery occlusion	4	0
Cerebral artery thrombosis	13	0
Cerebral haematoma	13	1
Cerebral haemorrhage	156	43
Cerebral infarction	85	5
Cerebral ischaemia	4	0
Cerebral thrombosis	32	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	1070	40
Embolic stroke	19	0
Haemorrhage intracranial	52	12

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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	39	6
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	128	6
Lacunar infarction	4	0
Lacunar stroke	23	0
Pseudostroke	1	0
Spinal cord haematoma	1	0
Spinal cord infarction	1	0
Spinal stroke	2	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	102	5
Thalamic infarction	1	0
Thalamus haemorrhage	8	0
Thrombotic stroke	11	0
Vertebral artery occlusion	1	0
Vertebral artery thrombosis	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	4	0
Central nervous system inflammation	12	0
Neurosarcoidosis	3	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	1
Brain stem microhaemorrhage	1	0
Carotid arteriosclerosis	1	0
Carotid artery stenosis	4	0
Central nervous system vasculitis	3	0
Cerebral amyloid angiopathy	2	0
Cerebral arteriosclerosis	2	0
Cerebral congestion	3	0
Cerebral microhaemorrhage	2	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	192	20
Cerebral venous thrombosis	48	5
Superior sagittal sinus thrombosis	28	3
Transverse sinus thrombosis	6	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	6	0
Choreiform movements		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
Chronic polyneuropathies		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	4	0
Demyelinating polyneuropathy	9	0
Diabetic neuropathy	2	0
Polyneuropathy chronic	1	0
Coma states		
Coma	19	0
Diabetic coma	3	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	37	0
Balance disorder	833	0
Cerebellar ataxia	2	0
Cerebellar syndrome	1	0
Coordination abnormal	118	0
Dysdiadochokinesis	1	0
Dysstasia	105	0
Hand-eye coordination impaired	1	0
Nystagmus	21	0
Cortical dysfunction NEC		
Agraphia	1	0
Alexia	6	0
Aphasia	137	0
Apraxia	1	0
Dysgraphia	8	0
Dyslexia	2	0
Dyspraxia	6	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	24	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	17	0
Neuromyelitis optica spectrum disorder	4	0
Disturbances in consciousness NEC		
Altered state of consciousness	14	0
Consciousness fluctuating	4	0
Depressed level of consciousness	82	0
Hypoglycaemic unconsciousness	1	0
Lethargy	4758	0
Loss of consciousness	1009	0
Postictal state	1	0
Sedation	15	0
Somnolence	1872	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Stupor	9	0
Syncope	2414	0
<i>Disturbances in sleep phase rhythm</i>		
Advanced sleep phase	1	0
Circadian rhythm sleep disorder	6	0
Delayed sleep phase	1	0
Irregular sleep phase	3	0
Irregular sleep wake rhythm disorder	1	0
Non-24-hour sleep-wake disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	10	0
Ballismus	1	0
Bradykinesia	31	0
Clumsiness	48	0
Dyskinesia	110	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	18	0
Hyperkinesia	27	0
Hypokinesia	68	0
Meige's syndrome	1	0
Motor dysfunction	14	0
Movement disorder	98	0
Psychomotor hyperactivity	37	0
Tardive dyskinesia	1	0
<i>Dystonias</i>		
Dystonia	20	0
Dystonic tremor	3	0
Opisthotonus	4	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Bickerstaff's encephalitis	1	0
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	4	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	4	1
Encephalopathy	6	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	3	0
<i>Encephalopathies toxic and metabolic</i>		
Hepatic encephalopathy	2	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	6	0
Microvascular cranial nerve palsy	2	0
VIth nerve paralysis	9	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	507	0
Facial nerve disorder	6	0
Facial paralysis	289	0
Facial paresis	143	0
Facial spasm	35	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Oculofacial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	86	0
Headaches NEC		
Cervicogenic headache	5	0
Chronic paroxysmal hemicrania	1	0
Cluster headache	703	0
Cold-stimulus headache	81	0
Drug withdrawal headache	16	0
Exertional headache	11	0
External compression headache	4	0
Headache	78908	4
Medication overuse headache	16	0
New daily persistent headache	19	0
Occipital neuralgia	21	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	932	0
Tension headache	1455	0
Thunderclap headache	45	0
Vascular headache	77	0
Hydrocephalic conditions		
Hydrocephalus	14	0
Hypoglossal nerve disorders		
Tongue paralysis	6	0
Increased intracranial pressure disorders		
Brain compression	3	0
Brain oedema	23	1
Cerebrospinal fluid circulation disorder	4	0
Cytotoxic oedema	1	0
Idiopathic intracranial hypertension	6	0
Intracranial pressure increased	21	0
Intellectual disabilities		
Intellectual disability	9	0
Lumbar spinal cord and nerve root disorders		
Lumbar radiculopathy	3	0
Sciatica	179	0
Memory loss (excl dementia)		
Amnesia	324	0
Memory impairment	301	0
Transient global amnesia	22	0
Meningitis NEC		
Meningitis noninfective	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	159	1
Disturbance in attention	662	0
Judgement impaired	3	0
Mental impairment	128	0
Migraine headaches		
Basilar migraine	5	0
Hemiplegic migraine	40	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Migraine	7175	0
Migraine with aura	357	0
Migraine without aura	47	0
Ophthalmic migraine	12	0
Retinal migraine	83	0
Status migrainosus	5	0
Typical aura without headache	18	0
Vestibular migraine	32	0
Mixed cranial nerve disorders		
Bulbar palsy	3	0
Mononeuropathies		
Carpal tunnel syndrome	29	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Meralgia paraesthetica	3	0
Mononeuritis	3	0
Mononeuropathy	2	0
Nerve compression	52	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	12	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	53	0
Multiple sclerosis relapse	47	0
Relapsing multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	0
Uhthoff's phenomenon	4	0
Muscle tone abnormal		
Drop attacks	1	0
Hypertonia	3	0
Hypotonia	33	0
Serotonin syndrome	1	0
Stiff leg syndrome	9	0
Myelitis (incl infective)		
Myelitis transverse	72	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	200	0
Narcolepsy	20	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	3	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Microglial nodules	1	0
Nervous system disorder	52	0
Neurotoxicity	3	0
Psychomotor skills impaired	4	0
Neurologic visual problems NEC		
Hemianopia	7	0
Hemianopia homonymous	1	0
Tunnel vision	19	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	21498	0
Dizziness exertional	96	0
Dizziness postural	2091	1
Drooling	22	0
Exaggerated startle response	4	0
Fontanelle bulging	3	0
Head discomfort	683	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	5	0
Intracranial hypotension	2	0
Meningism	2	0
Myoclonus	29	0
Neurological decompensation	4	0
Neurological symptom	106	0
Patient elopement	2	0
Persistent postural-perceptual dizziness	33	0
Pleocytosis	3	0
Presyncope	580	0
Sensory overload	11	0
Slow response to stimuli	6	0
Tongue biting	10	0
Unresponsive to stimuli	97	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	1	0
Muscle contractions involuntary	35	0
Muscle spasticity	27	0
Neuromuscular pain	6	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	14	0
Myasthenia gravis crisis	3	0
Olfactory nerve disorders		
Anosmia	294	0
Hyposmia	10	0
Parosmia	386	0
Optic nerve disorders NEC		
Optic neuritis	48	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	28	0
Burning sensation	889	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Burning sensation mucosal	3	0
Dysaesthesia	11	0
Formication	69	0
Hand-arm vibration syndrome	1	0
Hemianaesthesia	4	0
Hemiparaesthesia	2	0
Hyperaesthesia	264	0
Hypoaesthesia	5396	0
Lhermitte's sign	2	0
Paraesthesia	8921	0
Reversed hot-cold sensation	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	30	0
Hemiparesis	94	0
Hemiplegia	37	0
Monoparesis	90	0
Monoplegia	120	0
Paralysis	289	0
Paraparesis	6	0
Paraplegia	2	0
Paresis	7	0
Peripheral nerve palsy	1	0
Postictal paralysis	3	0
Quadriparesis	1	0
Quadriplegia	3	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	155	0
Parkinson's disease	15	0
Parkinsonism	10	0
Reduced facial expression	7	0
Vascular parkinsonism	1	0
<i>Partial complex seizures</i>		
Dreamy state	21	0
Focal dyscognitive seizures	7	0
Temporal lobe epilepsy	4	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	2	0
Simple partial seizures	7	0
<i>Peripheral neuropathies NEC</i>		
Autoimmune neuropathy	2	0
Axonal neuropathy	2	0
Ischaemic neuropathy	2	0
Neuralgic amyotrophy	6	0
Neuritis	13	0
Neuropathy peripheral	197	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	14	0
Polyneuropathy	11	0
Small fibre neuropathy	2	0
Thoracic outlet syndrome	2	0
<i>Seizures and seizure disorders NEC</i>		
Alcoholic seizure	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Atonic seizures	11	0
Change in seizure presentation	7	0
Clonic convulsion	10	0
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	2	0
Epilepsy	308	1
Epileptic aura	2	0
Febrile convulsion	93	0
Migraine-triggered seizure	2	0
Myoclonic epilepsy	5	0
Partial seizures	56	0
Psychogenic seizure	5	0
Seizure	1213	2
Seizure anoxic	3	0
Seizure cluster	8	0
Seizure like phenomena	2	0
Status epilepticus	26	2
Tonic clonic movements	3	0
Tonic convulsion	36	0
Sensory abnormalities NEC		
Ageusia	1018	0
Allodynia	58	0
Aura	25	0
Central pain syndrome	2	0
Complex regional pain syndrome	11	0
Decreased vibratory sense	1	0
Dysgeusia	1963	0
Electric shock sensation	84	0
Hypogeusia	5	0
Intercostal neuralgia	2	0
Loss of proprioception	3	0
Neuralgia	1264	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	18	0
Post herpetic neuralgia	11	0
Restless arm syndrome	12	0
Restless legs syndrome	372	0
Sensory disturbance	125	0
Sensory loss	210	0
Taste disorder	495	0
Vibratory sense increased	1	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	2	0
Periodic limb movement disorder	1	0
Sleep deficit	48	0
Speech and language abnormalities		
Dysarthria	393	0
Incoherent	17	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Slow speech	37	0
Speech disorder	98	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 14-Jul-2021 18:30:32
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Spinal cord and nerve root disorders NEC</i>		
Cauda equina syndrome	6	0
Myelopathy	4	0
Radicular pain	1	0
Radiculitis brachial	21	0
Radiculopathy	2	0
Spinal cord disorder	4	0
Spinal cord oedema	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	29	2
Cerebral mass effect	9	0
Intracranial mass	3	0
White matter lesion	2	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	434	0
<i>Tremor (excl congenital)</i>		
Action tremor	3	0
Asterixis	1	0
Essential tremor	6	0
Head titubation	19	0
Intention tremor	1	0
Postural tremor	1	0
Resting tremor	6	0
Tremor	9512	2
<i>Trigeminal disorders</i>		
Facial neuralgia	37	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	6	0
Trigeminal neuralgia	94	0
Trigeminal neuritis	2	0
Trigeminal palsy	1	0
<i>Vagus nerve disorders</i>		
Vagus nerve paralysis	1	0
Vocal cord paralysis	2	0
<i>Vertigos NEC</i>		
Vertigo CNS origin	2	0
Nervous system disorders SOC TOTAL	169722	180

Case Series Drug Analysis Print

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Report Run Date: 15-Jul-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

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	152	0
<i>Foetal complications NEC</i>		
Foetal disorder	2	0
<i>Foetal growth complications</i>		
Foetal growth restriction	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>High risk pregnancies</i>		
Risk of future pregnancy miscarriage	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 delivery NEC</i>		
Traumatic delivery	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	2	0
Uterine hypertonus	1	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	1	0
Decidual cast	2	0
Ectopic pregnancy	6	0
Hyperemesis gravidarum	2	0
Morning sickness	33	0
Pelvic girdle pain	2	0
Somatic symptom disorder of pregnancy	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Pregnancy	35	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>		
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	3	0
Unintended pregnancy	4	0

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Reaction Name	Total	Fatal
Pregnancy conditions Pregnancy conditions cont'd		
Pregnancy conditions SOC TOTAL	283	1

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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 expulsion	1	0
Device issue	4	0
Device leakage	2	0
<i>Device malfunction events NEC</i>		
Oversensing	25	0
Stent malfunction	1	0
Thrombosis in device	54	1
Undersensing	5	0
<i>Device physical property and chemical issues</i>		
Needle issue	11	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	5	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	141	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	22	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	6	0
Adjustment disorder with mixed anxiety and depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	12	0
Blunted affect	1	0
Constricted affect	9	0
Flat affect	10	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	190	0
Anxiety	1096	0
Immunisation anxiety related reaction	1	0
Nervousness	581	0
Procedural anxiety	1	0
Stress	130	0
Tension	67	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	18	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	12	0
Antisocial behaviour	1	0
Asocial behaviour	1	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	1	0
Homicidal ideation	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	7	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Change in sustained attention	1	0
Daydreaming	14	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Distractibility	2	0
Mental fatigue	450	0
Communications disorders		
Communication disorder	6	0
Mutism	5	0
Speech sound disorder	2	0
Confusion and disorientation		
Confusional state	1985	0
Disorientation	687	0
Decreased physical activity levels		
Catatonia	2	0
Deliria		
Delirium	462	0
Delirium febrile	3	0
Delusional disorders		
Alice in wonderland syndrome	3	0
Delusional symptoms		
Delusion	48	1
Delusion of parasitosis	2	0
Mixed delusion	1	0
Thought withdrawal	1	0
Dementia NEC		
Pseudodementia	1	0
Depressive disorders		
Agitated depression	3	0
Childhood depression	1	0
Depression	580	0
Depression suicidal	14	0
Major depression	23	0
Menopausal depression	2	0
Mixed anxiety and depressive disorder	2	0
Dissociative states		
Depersonalisation/derealisation disorder	18	0
Dissociation	69	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	40	0
Insomnia	2936	0
Middle insomnia	71	0
Terminal insomnia	22	0
Dyssomnias		
Dyssomnia	4	0
Poor quality sleep	640	0
Eating disorders NEC		
Binge eating	1	0
Eating disorder	12	0
Pica	1	0
Selective eating disorder	2	0
Emotional and mood disturbances NEC		
Anger	82	0
Dysphoria	2	0
Emotional disorder	93	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Emotional distress	71	0
Emotional poverty	2	0
Euphoric mood	63	0
Frustration tolerance decreased	10	0
Irritability	301	0
Mood altered	75	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	2	0
Agoraphobia	4	0
Fear	48	0
Fear of death	16	0
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	4	0
Fear of injection	2	0
Fear of open spaces	1	0
Performance fear	1	0
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	1	0
Social fear	1	0
Thanatophobia	1	0
Fluctuating mood symptoms		
Mood swings	108	0
Hallucinations (excl sleep-related)		
Hallucination	903	0
Hallucination, auditory	45	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	469	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Emotional disorder of childhood	1	0
Mental disorders NEC		
Mental disorder	21	0
Mental status changes	4	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	16	0
Depressed mood	622	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	17	0
Negative thoughts	9	0
Sense of a foreshortened future	2	0
Tearfulness	101	0
Mood alterations with manic symptoms		
Hypomania	1	0
Mania	30	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	67	0
Laziness	1	0
Listless	120	0
Mood disorder due to a general medical condition	1	0
Substance-induced mood disorder	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Sleep attacks	2	0
Obsessive-compulsive disorders and symptoms		
Body dysmorphic disorder	2	0
Compulsive shopping	2	0
Dermatillomania	2	0
Obsessive thoughts	3	0
Obsessive-compulsive disorder	2	0
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	3	0
Female orgasmic disorder	1	0
Orgasm abnormal	1	0
Orgasmic sensation decreased	4	0
Premature ejaculation	2	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	296	0
Panic disorder	5	0
Panic reaction	39	0
Paraphilias and paraphilic disorders		
Fetishism	2	0
Parasomnias		
Abnormal dreams	361	0
Abnormal sleep-related event	2	0
Confusional arousal	3	0
Exploding head syndrome	6	0
Nightmare	438	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	11	0
Perception disturbances NEC		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Autoscopy	26	0
Deja vu	4	0
Delusional perception	2	0
Derealisation	14	0
Flashback	2	0
Illusion	11	0
Imperception	1	0
Near death experience	1	0
Pseudohallucination	1	0
Time perception altered	5	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	54	0
Psychiatric symptoms NEC		
Helplessness	3	0
Hypervigilance	13	0
Psychiatric symptom	8	0
Psychological trauma	5	0
Psychotic disorder NEC		
Acute psychosis	5	0
Psychotic behaviour	2	0
Psychotic disorder	40	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		
Excessive masturbation	1	0
Hypersexuality	1	0
Libido decreased	19	0
Libido increased	8	0
Loss of libido	40	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	389	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	22	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

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Poverty of speech	1	0
Verbigeration	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	32	0
Lack of spontaneous speech	3	0
<i>Stereotypies and automatisms</i>		
Bruxism	34	0
Head banging	44	0
Waxy flexibility	2	0
<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	3	0
Alcoholic hangover	1	0
Alcoholism	3	0
Dependence	2	0
Drug abuse	1	0
Drug dependence	1	0
Substance abuse	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	3	3
Intentional self-injury	9	0
Self-injurious ideation	3	0
Suicidal behaviour	3	0
Suicidal ideation	105	0
Suicide attempt	29	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	88	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	26	0
Thought blocking	5	0
<i>Tic disorders</i>		
Secondary tic	1	0
Tic	15	0
Psychiatric disorders SOC TOTAL	16345	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	59	0
Bladder spasm	1	0
Dysuria	79	0
Incontinence	74	0
Micturition disorder	3	0
Micturition frequency decreased	1	0
Micturition urgency	98	0
Mixed incontinence	1	0
Pollakiuria	278	0
Urethral pain	6	0
Urge incontinence	2	0
Urinary hesitation	7	0
Urinary incontinence	110	0
Urinary retention	84	0
Urine flow decreased	18	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	17	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	13	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	9	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	5	0
Henoch-Schonlein purpura nephritis	1	0
IgA nephropathy	3	0
Nephrotic syndrome	15	0
<i>Myoneurogenic bladder disorders</i>		
Atonic urinary bladder	1	0
Automatic bladder	1	0
Bladder dysfunction	7	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>		

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
Oedematous kidney	1	0
Renal disorder	10	0
Renal haemorrhage	2	0
<i>Renal failure and impairment</i>		
Acute kidney injury	54	1
Anuria	5	0
Chronic kidney disease	9	0
End stage renal disease	1	0
Oliguria	11	0
Renal failure	32	2
Renal impairment	14	0
Renal injury	5	0
<i>Renal hypertension and related conditions</i>		
Hypertensive nephropathy	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	18	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
Renal atrophy	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal artery occlusion	1	0
Renal embolism	1	0
Renal infarct	13	1
Renal tubular injury	1	0
Renal vascular thrombosis	2	0
Renal vein embolism	1	0
Renal vein occlusion	3	0
Renal vein thrombosis	9	0
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral spasm	1	0
<i>Ureteric disorders NEC</i>		
Ureteral disorder	2	0
<i>Urinary abnormalities</i>		
Chromaturia	97	0
Glycosuria	1	0
Haematuria	58	0
Microalbuminuria	1	0
Proteinuria	9	0
Urine abnormality	17	0
Urine odour abnormal	20	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	52	0
Nocturia	20	0
Polyuria	33	0
Renal colic	3	0
Renal pain	904	0
Urinary tract discomfort	2	0
Urinary tract pain	15	0
Renal & urinary disorders SOC TOTAL	2400	5

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	9	0
<i>Breast disorders NEC</i>		
Breast disorder	2	0
Breast enlargement	8	0
Breast mass	60	0
Gynaecomastia	9	0
Mammary duct ectasia	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	4	0
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	9	0
Breast discolouration	1	0
Breast discomfort	11	0
Breast engorgement	6	0
Breast haemorrhage	1	0
Breast induration	1	0
Breast oedema	1	0
Breast pain	427	0
Breast swelling	61	0
Breast tenderness	66	0
Nipple exudate bloody	1	0
Nipple pain	35	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	74	0
Erection increased	6	0
Organic erectile dysfunction	19	0
Painful ejaculation	1	0
Painful erection	1	0
Priapism	3	0
Retrograde ejaculation	3	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	23	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal disorder	2	0
Menopausal symptoms	40	0
Menopause delayed	4	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Premature menopause	34	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	333	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	5	0
Abnormal withdrawal bleeding	5	0
Dysmenorrhoea	954	0
Intermenstrual bleeding	532	0
Menstrual discomfort	10	0
Menstrual disorder	1094	0
Menstruation irregular	1549	0
Premenstrual dysphoric disorder	5	0
Premenstrual headache	7	0
Premenstrual pain	57	0
Premenstrual syndrome	36	0
Retrograde menstruation	3	0
Withdrawal bleed	12	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	397	0
Hypomenorrhoea	329	0
Menstruation delayed	2359	0
Oligomenorrhoea	81	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	3478	0
Menometrorrhagia	13	0
Polymenorrhoea	456	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	14	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	31	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovarian enlargement	1	0
Ovarian failure	1	0
Ovarian haemorrhage	3	0
Ovarian hyperstimulation syndrome	1	0
Ovarian necrosis	1	0
Ovarian oedema	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	43	0
Premature ovulation	3	0
<i>Pelvic prolapse conditions</i>		
Pelvic prolapse	1	0
Vaginal prolapse	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	36	0
Pelvic haematoma	1	0
Pelvic haemorrhage	24	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	6	0
Penile burning sensation	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Penile curvature	4	0
Penile discharge	4	0
Penile exfoliation	1	0
Penile haemorrhage	7	0
Penile oedema	3	0
Penile pain	2	0
Penile size reduced	2	0
Penis disorder	9	0
Peyronie's disease	4	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	6	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatism	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Female genital tract fistula	1	0
Genital blister	4	0
Genital haemorrhage	27	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	2	0
Genital lesion	1	0
Genital paraesthesia	3	0
Genital ulceration	13	0
Perineal disorder	2	0
Varicose veins pelvic	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	2	0
<i>Reproductive tract neoplasms NEC</i>		
Genital cyst	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	8	0
Genital discomfort	3	0
Genital erythema	1	0
Genital pain	4	0
Genital rash	5	0
Genital swelling	1	0
Pelvic discomfort	3	0
Pelvic pain	147	0
Perineal pain	1	0
Pruritus genital	8	0
<i>Scrotal disorders NEC</i>		
Scrotal dermatitis	1	0
Scrotal oedema	1	0
Scrotal pain	13	0
Scrotal swelling	5	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	6	0
Female sexual dysfunction	1	0
Infertility	5	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Infertility female	1	0
Infertility male	2	0
Male sexual dysfunction	1	0
Sexual dysfunction	8	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	2	0
Haematospermia	15	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	99	0
Testicular retraction	2	0
Testicular swelling	18	0
Testis discomfort	5	0
<i>Testicular and epididymal neoplasms</i>		
Epididymal cyst	1	0
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	11	0
Endometrial thickening	1	0
Endometriosis	65	0
Metrorrhoea	1	0
Uterine enlargement	1	0
Uterine haemorrhage	53	0
Uterine pain	8	0
<i>Uterine neoplasms</i>		
Uterine cyst	1	0
Uterine polyp	3	0
<i>Uterine tone disorders</i>		
Uterine spasm	19	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	2	0
Vaginal cyst	13	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal disorder	1	0
Vaginal haemorrhage	1054	0
Vaginal ulceration	6	0
Vulval disorder	2	0
Vulval haemorrhage	26	0
Vulval ulceration	4	0
Vulvovaginal ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	6	0
Enlarged clitoris	1	0
Labia enlarged	2	0
Vaginal discharge	71	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vaginal lesion	6	0
Vaginal odour	4	0
Vulval oedema	1	0
Vulvovaginal burning sensation	7	0
Vulvovaginal discomfort	8	0
Vulvovaginal dryness	11	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	32	0
Vulvovaginal pruritus	11	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	6	0
Reproductive & breast disorders SOC TOTAL	14776	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	12	0
Apnoeic attack	1	0
Cheyne-Stokes respiration	1	0
Dyspnoea	6791	6
Dyspnoea at rest	15	0
Dyspnoea exertional	49	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	89	0
Hypopnoea	214	0
Hypoventilation	1	0
Irregular breathing	23	0
Mouth breathing	7	0
Orthopnoea	3	0
Respiration abnormal	95	0
Respiratory arrest	22	0
Respiratory distress	10	0
Respiratory fatigue	7	0
Sleep apnoea syndrome	28	0
Tachypnoea	36	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	558	0
Asthma exercise induced	2	0
Asthma late onset	3	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	2	0
Asthmatic crisis	5	0
Bronchitis chronic	1	0
Bronchospasm	18	0
Chronic obstructive pulmonary disease	42	4
Cough variant asthma	8	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	587	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Hypercapnia	1	0
Hypoxia	68	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	3752	0
Haemoptysis	129	0
Productive cough	185	0
Sputum discoloured	13	0
Sputum increased	1	0
Sputum retention	1	0
<i>Diaphragmatic disorders</i>		
Diaphragmatic spasm	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	2	0
Vocal cord disorder	5	0
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
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	23	6
Pneumonitis	30	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	46	0
Lower respiratory tract congestion	4	0
Lung opacity	6	0
Pleuritic pain	43	0
Pulmonary haemorrhage	7	1
Pulmonary pain	211	0
Rales	2	0
<i>Mediastinal disorders</i>		
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	447	0
Nasal inflammation	8	0
Rhinitis allergic	26	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2149	0
Intranasal hypoaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	7	0
Nasal dryness	57	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	13	0
Nasal polyps	1	0
Nasal pruritus	11	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	3	0
Nasal valve collapse	1	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

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	3	0
Sinonasal obstruction	10	0
Sinus congestion	88	0
Sinus disorder	15	0
Sinus polyp	3	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	6	0
Emphysema	3	0
Idiopathic pulmonary fibrosis	1	0
Interstitial lung disease	19	1
Lung consolidation	7	0
Lung cyst	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	3	0
Pulmonary fibrosis	8	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Oropharyngeal swelling	2	0
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	38	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	12	0
Pharyngeal paraesthesia	34	0
Pharyngeal swelling	270	0
Pharyngeal ulceration	15	0
Tonsillar disorder	1	0
Tonsillar erythema	7	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	63	0
Tonsillar inflammation	4	0
Tonsillar ulcer	2	0
Tonsilloolith	1	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pleural infections and inflammations</i>		
Lupus pleurisy	2	0
Pleurisy	45	0
<i>Pneumothorax and pleural effusions NEC</i>		
Haemothorax	1	0
Pleural effusion	36	1
Pneumothorax	8	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	3	1
<i>Pulmonary oedemas</i>		
Acute lung injury	1	0
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	17	0
Pulmonary oedema	30	1

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	1447	92
Pulmonary infarction	15	1
Pulmonary thrombosis	22	4
Pulmonary venous thrombosis	4	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
Respiratory failure	21	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	11	0
Diaphragmalgia	15	0
Nasal flaring	1	0
Painful respiration	9	0
Pleural rub	1	0
Respiratory symptom	19	0
Suffocation feeling	5	0
Use of accessory respiratory muscles	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	9	2
Chronic respiratory disease	2	1
Lung disorder	7	0
Pulmonary mass	6	0
Respiratory disorder	8	0
Respiratory tract congestion	7	0
Respiratory tract haemorrhage	2	0
Respiratory tract irritation	10	0
Respiratory tract oedema	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal fistula	1	0
Tracheal pain	4	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	100	0
Catarrh	59	0
Choking	20	0
Choking sensation	9	0
Dry throat	250	0
Dysphonia	151	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	110	0
Nasal obstruction	1	0
Oropharyngeal blistering	26	0
Oropharyngeal discomfort	36	0
Oropharyngeal pain	4085	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	69	0
Rhinalgia	33	0
Rhinorrhoea	1626	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Sinus pain	581	0
Sneezing	478	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	198	0
Throat lesion	1	0
Throat tightness	207	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	25	0
Yawning	65	0
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	26558	126

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	118	0
Acne cystic	9	0
Dermatitis acneiform	10	0
<i>Alopecias</i>		
Alopecia	311	0
Alopecia areata	24	0
Alopecia scarring	2	0
Alopecia totalis	1	0
Alopecia universalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Madarosis	3	0
<i>Angioedemas</i>		
Angioedema	334	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1669	0
Hidradenitis	1	0
Hyperhidrosis	8957	0
Hypohidrosis	3	0
Miliaria	213	0
Night sweats	1830	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	530	0
Blister rupture	7	0
Blood blister	104	0
Dermatitis bullous	14	0
Dermatitis herpetiformis	2	0
Erythema multiforme	37	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	25	0
Pemphigus	1	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	2	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	3	0
Dry skin	416	0
Macule	13	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	905	0
Papule	114	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Peau d'orange	3	0
Scab	25	0
Scar pain	15	0
Sensitive skin	567	0
Skin burning sensation	546	0
Skin discolouration	182	0
Skin discomfort	6	0
Skin disorder	27	0
Skin fissures	12	0
Skin fragility	2	0
Skin indentation	15	0
Skin induration	16	0
Skin laxity	1	0
Skin lesion	47	0
Skin necrosis	5	0
Skin odour abnormal	48	0
Skin plaque	3	0
Skin reaction	259	0
Skin sensitisation	88	0
Skin swelling	93	0
Skin texture abnormal	1	0
Skin tightness	34	0
Skin warm	565	0
Skin weeping	7	0
Sticky skin	7	0
Target skin lesion	2	0
Transient acantholytic dermatosis	2	0
Yellow skin	30	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	178	0
Dermatitis allergic	302	0
Dermatitis atopic	26	0
Dermatitis contact	24	0
Dermatitis diaper	3	0
Dyshidrotic eczema	10	0
Eczema	295	0
Eczema asteatotic	17	0
Eczema nummular	3	0
Eczema weeping	2	0
Hand dermatitis	6	0
Intertrigo	2	0
Neurodermatitis	1	0
Perioral dermatitis	5	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	9	0
Skin irritation	145	0
Stasis dermatitis	5	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	35	0
Drug reaction with eosinophilia and systemic symptoms	14	0
Fixed eruption	5	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Palmar-plantar erythrodysesthesia syndrome	2	0
Erythemas		
Erythema	3258	0
Erythema ab igne	1	0
Palmar erythema	6	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	15	0
Skin exfoliation	152	0
Granulomatous and deep cutaneous inflammatory conditions		
Granuloma annulare	4	0
Hyperkeratoses		
Hyperkeratosis	2	0
Hyperpigmentation disorders		
Chloasma	1	0
Ephelides	1	0
Melanoderma	2	0
Skin hyperpigmentation	9	0
Solar lentigo	6	0
Hypertrichoses		
Hypertrichosis	2	0
Hypopigmentation disorders		
Skin depigmentation	10	0
Skin hypopigmentation	3	0
Vitiligo	22	0
Lipodystrophies		
Lipoatrophy	2	0
Lipohypertrophy	2	0
Nail and nail bed conditions (excl infections and infestations)		
Anonychia	1	0
Ingrowing nail	2	0
Nail bed disorder	2	0
Nail bed inflammation	1	0
Nail bed tenderness	2	0
Nail discolouration	10	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	7	0
Onychalgia	5	0
Onychoclasia	9	0
Onycholysis	2	0
Onychomadesis	3	0
Splinter haemorrhages	5	0
Panniculitides		
Erythema nodosum	34	0
Panniculitis	4	0
Papulosquamous conditions		
Erythema annulare	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Lichen planus	25	0
Lichen sclerosus	5	0
Parapsoriasis	2	0
Pityriasis rosea	61	0
Pityriasis rubra pilaris	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photodermatosis	2	0
Photosensitivity reaction	156	0
Polymorphic light eruption	6	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	15	0
<i>Pilar disorders NEC</i>		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	7	0
Hair texture abnormal	8	0
Piloerection	94	0
Pseudofolliculitis	1	0
Trichodynia	6	0
Trichorrhexis	2	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	7797	0
Pruritus allergic	1	0
Senile pruritus	1	0
<i>Psoriatic conditions</i>		
Erythrodermic psoriasis	1	0
Guttate psoriasis	27	0
Nail psoriasis	1	0
Palmoplantar pustulosis	1	0
Psoriasis	189	0
Pustular psoriasis	4	0
<i>Purpura and related conditions</i>		
Ecchymosis	5	0
Henoch-Schonlein purpura	15	0
Petechiae	343	0
Purpura	132	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	8	0
Rash	8535	0
Rash erythematous	2174	0
Rash macular	715	0
Rash maculo-papular	65	0
Rash morbilliform	46	0
Rash papular	547	0
Rash pruritic	1847	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	93	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	3	0
Granulomatous rosacea	1	0
Rosacea	42	0
Scaly conditions		
Pityriasis	11	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	11	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	11	0
Skin discharge	1	0
Skin mass	39	0
Skin and subcutaneous tissue ulcerations		
Diabetic foot	2	0
Diabetic ulcer	1	0
Pyoderma gangrenosum	2	0
Skin erosion	46	0
Skin ulcer	28	0
Skin cysts and polyps		
Dermal cyst	20	0
Skin dystrophies		
Keloid scar	1	0
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	17	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	42	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	8	0
Skin striae	12	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
Haemangioma-thrombocytopenia syndrome	1	0
Skin oedema	3	0
Skin vasculitides		
Cutaneous vasculitis	10	0
Hypersensitivity vasculitis	4	0
Vasculitic rash	25	1
Skin vasomotor conditions		
Livedo reticularis	56	0
Telangiectasia and related conditions		
Spider naevus	4	0
Telangiectasia	3	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 15-Jul-2021

Data Lock Date: 14-Jul-2021 18:30:32

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Urticarias</i>		
Chronic spontaneous urticaria	4	0
Cold urticaria	5	0
Idiopathic urticaria	9	0
Mechanical urticaria	3	0
Solar urticaria	1	0
Urticaria	2366	0
Urticaria chronic	37	0
Urticaria contact	2	0
Urticaria papular	3	0
Urticaria pigmentosa	1	0
Urticaria thermal	6	0
Urticularial vasculitis	4	0
Skin disorders SOC TOTAL	48834	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	3	0
Menopause	50	0
Postmenopause	14	0
<i>Alcohol product use</i>		
Alcoholic	3	0
<i>Bereavement issues</i>		
Death of pet	1	1
Death of relative	1	1
<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	87	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	47	0
Immobilisation prolonged	4	0
Impaired driving ability	4	0
Impaired work ability	18	0
Loss of personal independence in daily activities	7	0
Paralytic disability	1	0
Physical disability	1	0
Sight disability	20	0
Sitting disability	2	0
Walking aid user	1	0
Walking disability	2	0
<i>Educational issues</i>		
Educational problem	1	0
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	4	0
<i>Pregnancy related circumstances</i>		
Breast feeding	8	0
<i>Sexuality issues</i>		
Anal sex	1	0
Homosexuality	1	0

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
<i>Social issues NEC</i>		
Blood donor	2	0
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
Hair dye user	1	0
Impaired quality of life	1	0
Refusal of vaccination	3	0
Tanning	2	0
Tattoo	1	0
<i>Tobacco use</i>		
Non-tobacco user	5	0
Tobacco user	2	0
Social circumstances SOC TOTAL	329	2

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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>		
Antibiotic therapy	2	0
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>Chemotherapies</i>		
Chemotherapy toxicity attenuation	1	0
<i>Contraceptive methods female</i>		
Contraception	2	0
Contraceptive diaphragm	3	0
Oral contraception	2	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	3	0
<i>Dietary and nutritional therapies</i>		
Fluid replacement	1	0
Medical diet	5	0
Nothing by mouth order	6	0
<i>External ear therapeutic procedures</i>		
Cerumen removal	2	0
<i>Eye therapeutic procedures NEC</i>		
Eye drop instillation	1	0
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

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Gastric therapeutic procedures</i>		
Antacid therapy	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal resection	1	0
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	28	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	3	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	5	0
Hormone therapy	8	0
<i>Immunisations</i>		
COVID-19 immunisation	201	1
Immunisation	99	0
Tuberculosis immunisation	1	0
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Iris and ciliary body therapeutic procedures</i>		
Pupil constriction procedure	1	0
<i>Joint therapeutic procedures</i>		
Hip surgery	1	0
Joint injection	2	0
Joint stabilisation	2	0
Knee operation	2	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	6	0
Colectomy	1	0
<i>Limb therapeutic procedures</i>		
Arm amputation	1	0
Foot amputation	1	0
Leg amputation	3	0
Limb immobilisation	26	0
Limb operation	10	0
Limb reattachment surgery	1	0
Toe amputation	4	0
<i>Mastectomies</i>		
Breast conserving surgery	2	0
<i>Muscle therapeutic procedures</i>		
Muscle relaxant therapy	3	0
<i>Nail therapeutic procedures</i>		
Nail operation	2	0
<i>Nasal therapeutic procedures</i>		
Nasal irrigation	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	3	0
Multiple sclerosis relapse prophylaxis	1	0
<i>Orbit and globe therapeutic procedures</i>		

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Eye muscle operation	1	0
Patient positioning		
Prone position	1	0
Peripheral nerve therapeutic procedures		
Carpal tunnel decompression	1	0
Phototherapies		
UV light therapy	1	0
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
Respiratory tract therapeutic procedures NEC		
Respiratory therapy	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	4	0
Antiallergic therapy	1	0
Bed rest	24	0
Catheter management	4	0
Catheter placement	1	0
Continuous passive motion machine therapy	1	0
Fatigue management	1	0
Heat therapy	2	0
Hospitalisation	25	0
Immobilisation bandage	1	0
Injection	42	0
Interchange of vaccine products	9	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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgery	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0
Transgender operation	1	0
Tumour excision	1	0
<i>Tonsillar therapeutic procedures</i>		
Tonsillectomy	1	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	3	0
Hysterectomy	1	0
<i>Vascular therapeutic procedures NEC</i>		
Thrombectomy	2	0
Thrombolysis	2	0
<i>Venous therapeutic procedures</i>		
Phlebotomy	2	0
Surgical & medical procedures SOC TOTAL	677	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	12	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	11	2
Aneurysm ruptured	1	0
Artery dissection	2	0
Venous aneurysm	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	6	0
Aortic dissection	4	1
Aortic intramural haematoma	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	24	1
Aortic thrombosis	13	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	56	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	21	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	10	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	106	1
Distributive shock	2	0
Hypoperfusion	3	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	4	0
Shock	54	1
Shock haemorrhagic	1	0
Shock symptom	5	0
<i>Haemorrhages NEC</i>		
Bloody discharge	16	0
Haematoma	100	0
Haemorrhage	1183	1
Internal haemorrhage	28	0
Venous haemorrhage	8	0
<i>Lymphangiopathies</i>		
Lymphocele	2	0
Lymphorrhoea	1	0
<i>Lymphoedemas</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Lymphoedema	63	0
<i>Non-site specific embolism and thrombosis</i>		
Air embolism	1	0
Arterial thrombosis	23	0
Atheroembolism	1	0
Embolism	255	3
Embolism arterial	3	0
Embolism venous	12	1
Microembolism	3	0
Paradoxical embolism	1	0
Post thrombotic syndrome	1	0
Thrombophlebitis migrans	2	0
Thrombosis	1518	29
Venous thrombosis	33	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	14	0
Arterial spasm	2	0
Arterial stenosis	1	0
Arteriosclerosis	5	0
Haemorrhagic infarction	1	0
Infarction	9	0
Ischaemia	12	0
Peripheral venous disease	7	0
Vascular compression	1	0
Vascular occlusion	1	0
Vasospasm	10	0
<i>Non-site specific vascular disorders NEC</i>		
Angiopathy	2	0
Arterial rupture	1	0
Capillary fragility	10	0
Collateral circulation	1	0
Haemodynamic instability	4	0
Hyperaemia	2	0
Neovascularisation	1	0
Superficial vein prominence	6	0
Vascular pain	115	0
Vascular rupture	1	0
Vascular wall discolouration	1	0
Vasodilatation	108	0
Vein collapse	2	0
Vein discolouration	8	0
Vein disorder	22	0
Vein rupture	15	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	35	0
Deep vein thrombosis	1071	9
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	23	0
Pelvic venous thrombosis	17	1

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Peripheral artery thrombosis	17	0
Peripheral embolism	8	0
Peripheral vein thrombus extension	1	0
Subclavian artery embolism	1	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	3	0
Thrombophlebitis	118	0
Thrombophlebitis superficial	62	0
Venous thrombosis limb	4	0
Peripheral vascular disorders NEC		
Cyanosis	103	0
Erythromelalgia	7	0
Flushing	680	0
Hot flush	2075	0
Peripheral vascular disorder	5	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Dry gangrene	1	0
Extremity necrosis	2	0
Iliac artery occlusion	1	0
Intermittent claudication	5	0
Ischaemic limb pain	5	0
Jugular vein occlusion	2	0
Peripheral arterial occlusive disease	4	0
Peripheral artery occlusion	8	0
Peripheral coldness	1251	0
Peripheral ischaemia	32	2
Poor peripheral circulation	51	0
Raynaud's phenomenon	137	0
Phlebitis NEC		
Phlebitis	59	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	405	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	2	0
Spider vein	16	0
Varicophlebitis	8	0
Varicose ulceration	1	0
Varicose vein	133	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	5	0
Hypertension	863	0
Labile hypertension	1	0
Systolic hypertension	3	0
Venous hypertension	3	0
White coat hypertension	11	0
Vascular hypotensive disorders		
Capillary leak syndrome	8	0

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Reaction Name	Total	Fatal
Vascular disorders <i>Vascular disorders cont'd</i>		
Diastolic hypotension	1	0
Hypotension	518	0
Orthostatic hypotension	44	0
<i>Vascular malformations and acquired anomalies</i>		
Arteriovenous fistula	1	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	3	0
Diffuse vasculitis	2	1
MAGIC syndrome	3	1
Vasculitis	101	2
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	5	1
Vascular disorders SOC TOTAL	11934	59
TOTAL REACTIONS FOR DRUG	794545	999
TOTAL REPORTS	222291	
TOTAL FATAL OUTCOME REPORTS		999