

COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Data Lock Date: 09-Jun-2021 19:00:03

All UK spontaneous reports received up to and including 09/06/2021 for COVID-19 vaccine 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 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	9	0
Iron deficiency anaemia	9	0
Pernicious anaemia	2	0
<i>Anaemias NEC</i>		
Anaemia	85	0
Blood loss anaemia	2	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	8	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	3	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	94	0
Spontaneous haematoma	7	0
Spontaneous haemorrhage	1	0
<i>Coagulation factor deficiencies</i>		
Hypofibrinogenaemia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	8	0
Antiphospholipid syndrome	23	0
Coagulopathy	47	0
Disseminated intravascular coagulation	17	2
Hypercoagulation	19	1
<i>Eosinophilic disorders</i>		
Eosinophilia	17	0
Hypereosinophilic syndrome	1	0
<i>Haematological cysts and polyps</i>		
Splenic cyst	1	0
<i>Haematological disorders</i>		
Blood disorder	8	0
Bone marrow disorder	2	0
Bone marrow oedema	1	0
Mast cell activation syndrome	5	0
Mastocytosis	1	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	8	0
<i>Leukocytoses NEC</i>		
Leukocytosis	3	0
Lymphocytosis	8	0
Monocytosis	2	0
Neutrophilia	13	0
<i>Leukopenias NEC</i>		
Leukopenia	9	0
Lymphopenia	8	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	1	0

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Blood disorders Blood disorders cont'd		
Lymph node fibrosis	1	0
Lymph node pain	507	0
Lymphadenitis	28	0
Lymphadenopathy	4368	0
Lymphatic disorder	1	0
Pseudolymphoma	3	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Myelosuppression	3	0
Pancytopenia	17	0
<i>Neutropenias</i>		
Agranulocytosis	4	0
Autoimmune neutropenia	1	0
Febrile neutropenia	1	0
Neutropenia	73	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	3	0
Platelet disorder	7	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	2	0
Stress polycythaemia	3	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	4	0
<i>Red blood cell abnormal findings NEC</i>		
Anisocytosis	2	0
Macrocytosis	2	0
Poikilocytosis	1	0
Polychromasia	3	0
Rouleaux formation	1	0
<i>Sickle cell trait and disorders</i>		
Sickle cell anaemia with crisis	5	0
<i>Spleen disorders</i>		
Spleen disorder	1	0
Splenic artery thrombosis	2	0
Splenic haemorrhage	1	0
Splenic infarction	12	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	9	0
Splenomegaly	4	0
<i>Thrombocytopenias</i>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	12	0
Immune thrombocytopenia	191	1
Thrombocytopenia	759	5
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	2	0
<i>Thrombocytoses</i>		
Thrombocytosis	10	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	6490	9

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	16	0
Atrioventricular block complete	3	0
Atrioventricular block first degree	1	0
Atrioventricular block second degree	4	0
Brugada syndrome	1	0
Bundle branch block	1	0
Bundle branch block left	6	0
Bundle branch block right	2	0
Long QT syndrome	1	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	4	2
Atrial thrombosis	3	0
Cardiac disorder	52	0
Cardiac dysfunction	1	0
Cardiac ventricular thrombosis	9	2
Cardiovascular disorder	8	1
Cardiovascular insufficiency	10	0
Intracardiac thrombus	6	1
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	12	0
Cardiovascular symptom	2	0
Palpitations	4445	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	9	1
Congestive cardiomyopathy	8	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	2	1
Coronary artery disease	7	0
Coronary artery dissection	1	0
Coronary artery embolism	1	0
Coronary artery occlusion	1	0
Coronary artery thrombosis	10	2
<i>Heart failures NEC</i>		
Cardiac failure	50	7
Cardiac failure acute	5	0
Cardiac failure chronic	1	1
Cardiac failure congestive	2	1
Cardiogenic shock	8	2
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		

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Cardiac disorders Cardiac disorders cont'd		
Acute coronary syndrome	7	0
Acute myocardial infarction	54	8
Angina pectoris	166	0
Angina unstable	13	0
Arteriospasm coronary	5	0
Microvascular coronary artery disease	2	0
Myocardial infarction	294	38
Myocardial ischaemia	20	8
Prinzmetal angina	1	0
Left ventricular failures		
Acute left ventricular failure	1	0
Left ventricular failure	2	1
Mitral valvular disorders		
Mitral valve incompetence	6	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiomegaly	12	0
Diastolic dysfunction	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	13	0
Left ventricular hypertrophy	1	0
Myocardial rupture	1	0
Right atrial dilatation	1	0
Right ventricular dilatation	1	0
Right ventricular dysfunction	3	0
Ventricular hypertrophy	4	1
Noninfectious myocarditis		
Myocarditis	34	1
Noninfectious pericarditis		
Pericarditis	61	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	19	0
Pericardial haemorrhage	4	2
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	107	1
Bradycardia	69	0
Cardiac fibrillation	4	0
Cardiac flutter	180	0
Extrasystoles	110	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	11	0
Tachyarrhythmia	10	0
Tachycardia	1148	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	3	1
Supraventricular arrhythmias		
Arrhythmia supraventricular	13	0
Atrial fibrillation	256	0

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Cardiac disorders Cardiac disorders cont'd		
Atrial flutter	27	0
Atrial tachycardia	2	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	2	0
Sinus node dysfunction	1	0
Sinus tachycardia	62	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	30	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	139	31
Cardio-respiratory arrest	2	1
Pulseless electrical activity	5	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	8	0
Ventricular fibrillation	6	0
Ventricular tachycardia	13	0
Cardiac disorders SOC TOTAL	7658	118

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Arterial disorders congenital</i>		
Congenital arterial malformation	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	6	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	3	0
Ventricular septal defect	1	0
<i>Central nervous system disorders congenital NEC</i>		
Encephalocele	1	0
Neural tube defect	1	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	0
Congenital hydrocephalus	1	0
<i>Coagulation disorders congenital</i>		
Factor VII deficiency	1	0
Protein C deficiency	2	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	1	0
Micropenis	2	0
Penoscrotal fusion	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Limb reduction defect	2	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	1	0
<i>Ocular disorders congenital NEC</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Colour blindness	1	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
<i>Vascular anomalies congenital NEC</i>		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	66	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	24	0
Ear discomfort	92	0
Ear disorder	10	0
Ear haemorrhage	11	0
Ear pain	1811	0
Ear pruritus	5	0
Ear swelling	65	0
Otorrhoea	6	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	1	0
Eustachian tube obstruction	6	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	27	0
External ear pain	11	0
Red ear syndrome	5	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	7	0
<i>Hearing losses</i>		
Deafness	274	0
Deafness bilateral	13	0
Deafness neurosensory	19	0
Deafness transitory	3	0
Deafness unilateral	42	0
Hypoacusis	170	0
Neurosensory hypoacusis	1	0
Sudden hearing loss	50	0
<i>Hyperacusia</i>		
Hyperacusis	118	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	5	0
Meniere's disease	22	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	100	0
Phobic postural vertigo	2	0
Tinnitus	3184	0
Vertigo	1725	0
Vertigo labyrinthine	11	0
Vertigo positional	105	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	1	0
Middle ear effusion	3	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	4	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Ear disorders SOC TOTAL	7953	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	6	0
Thyroiditis	9	0
Thyroiditis acute	4	0
Thyroiditis chronic	1	0
Thyroiditis subacute	1	0
<i>Adrenal cortical hyperfunctions</i>		
Cushing's syndrome	1	0
Cushingoid	5	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	15	0
Adrenocortical insufficiency acute	29	0
Glucocorticoid deficiency	1	0
Secondary adrenocortical insufficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
Adrenal haemorrhage	7	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
Adrenomegaly	1	0
Haemorrhagic adrenal infarction	3	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	2	0
<i>Ectopic endocrine disorders</i>		
Carcinoid syndrome	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
Premature menarche	6	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	10	0
Ovulation delayed	7	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	2	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	3	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Hypothalamo-pituitary disorder	1	0
Pituitary apoplexy	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	7	0
Inappropriate antidiuretic hormone secretion	1	0
<i>Thyroid disorders NEC</i>		
Goitre	14	0
Thyroid disorder	13	0
Thyroid mass	3	0
Thyroid pain	12	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	4	0
Hyperthyroidism	29	0
Thyrotoxic crisis	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	41	0

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Reaction Name	Total	Fatal
Endocrine disorders Endocrine disorders cont'd		
Endocrine disorders SOC TOTAL	249	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	8	0
<i>Cataract conditions</i>		
Cataract	13	0
Cataract cortical	3	0
Cataract subcapsular	3	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	3	0
Vitreous detachment	41	0
Vitreous floaters	139	0
Vitreous opacities	1	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	17	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	110	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	2	0
Ulcerative keratitis	2	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal perforation	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	111	0
Excessive eye blinking	7	0
Eyelid ptosis	39	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	3	0
Glaucoma	8	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	7	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	20	0
Iritis	11	0
Uveitis	33	0
<i>Lacrimation disorders</i>		
Dry eye	259	0
Lacrimation increased	218	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	2	0
Eyelid haematoma	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	19	0
Chalazion	2	0
Eczema eyelids	2	0
Erythema of eyelid	6	0
Eyelid cyst	13	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eyelid irritation	4	0
Eyelid margin crusting	1	0
Eyelid oedema	12	0
Eyelid rash	10	0
Swelling of eyelid	110	0
Lid, lash and lacrimal structural disorders		
Eyelid exfoliation	2	0
Eyelid skin dryness	4	0
Eyelid thickening	3	0
Growth of eyelashes	5	0
Lagophthalmos	3	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	3	0
Eye haemorrhage	86	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	3	0
Ocular cysts and polyps		
Vitreous cyst	1	0
Ocular disorders NEC		
Dark circles under eyes	7	0
Eye disorder	24	0
Eye oedema	15	0
Eye pain	3053	0
Eye swelling	533	0
Eye symptom	9	0
Eye ulcer	9	0
Eyelid disorder	10	0
Eyelid pain	16	0
Eyelids pruritus	9	0
Ocular discomfort	60	0
Periorbital discomfort	1	0
Periorbital oedema	16	0
Periorbital pain	3	0
Periorbital swelling	89	0
Retinal disorder	1	0
Ocular infections, inflammations and associated manifestations		
Autoimmune eye disorder	1	0
Eye allergy	25	0
Eye discharge	22	0
Eye inflammation	27	0
Eye irritation	187	0
Eye pruritus	263	0
Limbal swelling	6	0
Ocular hyperaemia	382	0
Ocular rosacea	1	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	10	0
Eye movement disorder	41	0
Gaze palsy	3	0
Ocular myasthenia	2	0
Ophthalmoplegia	1	0
Strabismus	5	0
Ocular sensation disorders		

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Eye disorders Eye disorders cont'd		
Abnormal sensation in eye	24	0
Asthenopia	321	0
Eye paraesthesia	5	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	35	0
Hypoaesthesia eye	26	0
Photophobia	918	0
<i>Optic disc abnormalities NEC</i>		
Optic atrophy	1	0
Optic discs blurred	2	0
Papilloedema	10	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic disc haemorrhage	2	0
Optic ischaemic neuropathy	10	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	3	0
<i>Pupil disorders</i>		
Miosis	11	0
Mydriasis	28	0
Pupil fixed	11	0
Pupils unequal	10	0
<i>Refractive and accommodative disorders</i>		
Altered visual depth perception	5	0
Hypermetropia	1	0
Myopia	2	0
Refraction disorder	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal aneurysm	1	0
Retinal artery embolism	3	0
Retinal artery occlusion	18	0
Retinal haemorrhage	12	0
Retinal infarction	1	0
Retinal vascular occlusion	2	0
Retinal vascular thrombosis	2	0
Retinal vein occlusion	62	0
Retinal vein thrombosis	6	0
Retinal vein varices	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular cyst	1	0
Macular degeneration	8	0
Macular detachment	1	0
Macular hole	2	0
Neovascular age-related macular degeneration	10	0
Retinal detachment	20	0
Retinal drusen	1	0
Retinal tear	11	0
Retinal toxicity	5	0
Vitreoretinal traction syndrome	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Macular oedema	4	0
Retinal oedema	1	0
<i>Retinopathies NEC</i>		
Acute macular outer retinopathy	4	0

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Eye disorders Eye disorders cont'd		
Acute zonal occult outer retinopathy	1	0
Retinal exudates	14	0
Retinopathy	6	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	13	0
Scleritis	7	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	1	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Deposit eye	1	0
Endocrine ophthalmopathy	3	0
Exophthalmos	4	0
<i>Visual colour distortions</i>		
Chloropsia	1	0
Chromatopsia	1	0
Cyanopsia	2	0
Erythropsia	4	0
Xanthopsia	9	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0
Diplopia	274	0
Dysmetropsia	1	0
Halo vision	12	0
Metamorphopsia	29	0
Oscillopsia	1	0
Photopsia	279	0
Scintillating scotoma	6	0
Vision blurred	2432	0
Visual brightness	9	0
Visual snow syndrome	4	0
<i>Visual field disorders</i>		
Visual field defect	25	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	8	0
Blindness	229	0
Blindness day	1	0
Blindness transient	20	0
Blindness unilateral	24	0
Central vision loss	2	0
Night blindness	4	0
Sudden visual loss	5	0
Visual acuity reduced	28	0
Visual acuity reduced transiently	1	0
Visual impairment	584	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	2	0
Optic neuropathy	7	0
Eye disorders SOC TOTAL	11857	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	4	0
Gastrointestinal sounds abnormal	19	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	32	1
Pancreatitis acute	16	0
Pancreatitis chronic	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
<i>Anal and rectal pains</i>		
Proctalgia	25	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	2	0
Anal hypoaesthesia	4	0
Anal inflammation	1	0
Anal paraesthesia	1	0
Anal pruritus	5	0
Anal spasm	1	0
Anorectal discomfort	6	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal spasm	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	2	0
Colitis	41	0
Colitis ischaemic	5	1
Colitis microscopic	4	0
Colitis ulcerative	74	0
Crohn's disease	69	0
Inflammatory bowel disease	9	0
Terminal ileitis	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	3	0
<i>Dental disorders NEC</i>		
Diastema	1	0
Loose tooth	1	0
Malpositioned teeth	1	0
Teething	20	0
Tooth disorder	2	0
Tooth socket haemorrhage	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	12	0
Dental paraesthesia	16	0
Hyperaesthesia teeth	49	0
Hypoaesthesia teeth	2	0
Toothache	289	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Dental surface disorders</i>		
Tooth discolouration	15	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	12	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	8043	0
Diarrhoea haemorrhagic	29	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	1	0
Duodenal ulcer haemorrhage	2	1
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	767	0
Epigastric discomfort	18	0
Eructation	91	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	17	0
Faecaloma	3	0
Faeces discoloured	44	0
Faeces hard	4	0
Faeces pale	6	0
Faeces soft	19	0
Mucous stools	13	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	455	0
Flatulence	362	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	7	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	10	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	3	0
Gastritis	78	0
Reflux gastritis	14	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	3	0
Abdominal pain	4046	0
Abdominal pain lower	211	0
Abdominal pain upper	4629	0
Abdominal rigidity	50	0
Abdominal tenderness	18	0
Gastrointestinal pain	284	0
Oesophageal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	397	0
Duodenogastric reflux	2	0
Gastric dilatation	16	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastroesophageal reflux disease	188	0
Impaired gastric emptying	5	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	9	0
Gastric disorder	8	0
Gastrointestinal disorder	26	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	1	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	4	0
Change of bowel habit	15	0
Defaecation disorder	1	0
Dyschezia	13	0
Gastrointestinal motility disorder	3	0
Oesophageal achalasia	2	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	1436	0
Abdominal symptom	5	0
Acute abdomen	14	0
Anal incontinence	37	0
Breath odour	22	0
Dysphagia	206	0
Intestinal congestion	1	0
Odynophagia	29	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	2	1
Defaecation urgency	14	0
Frequent bowel movements	40	0
Irritable bowel syndrome	110	0
Oesophageal spasm	6	0
<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>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastrointestinal perforation	1	0
Gastrointestinal ulcer	1	0
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	7	0
Gastrointestinal vascular occlusion and infarction		
Intestinal infarction	4	0
Intestinal ischaemia	24	1
Mesenteric artery embolism	1	0
Mesenteric artery thrombosis	3	0
Mesenteric vein thrombosis	14	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	3	0
Visceral venous thrombosis	11	1
Gingival disorders, signs and symptoms NEC		
Epulis	1	0
Gingival atrophy	1	0
Gingival blister	22	0
Gingival discomfort	5	0
Gingival disorder	12	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	208	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	46	0
Gingival ulceration	8	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	20	0
Gingival haemorrhages		
Gingival bleeding	132	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoidal haemorrhage	2	0
Haemorrhoids	52	0
Haemorrhoids thrombosed	10	0
Inguinal hernias		
Inguinal hernia	3	0
Intestinal haemorrhages		
Anal haemorrhage	31	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	2	0
Rectal haemorrhage	92	0
Small intestinal haemorrhage	26	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	3	0
Large intestine perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal obstruction	1	0
Large intestinal stenosis	1	0
Malabsorption syndromes		
Bile acid malabsorption	1	0
Coeliac disease	16	0
Steatorrhoea	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Nausea and vomiting symptoms</i>		
Acetonaemic vomiting	1	0
Discoloured vomit	17	0
Faecal vomiting	3	0
Infantile vomiting	2	0
Nausea	31276	0
Regurgitation	2	0
Retching	220	0
Vomiting	10497	3
Vomiting projectile	146	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	25	0
Haematemesis	70	0
Haematochezia	80	0
Intra-abdominal haematoma	1	0
Melaena	7	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>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	3	0
Oesophagitis	15	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	4	0
Dry mouth	1069	0
Lip dry	74	0
Saliva altered	6	0
Saliva discolouration	1	0
Salivary hypersecretion	73	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	3	0
Chapped lips	19	0
Cheilitis	34	0
Chronic cheek biting	1	0
Enlarged uvula	11	0
Leukoplakia oral	2	0
Lip blister	32	0
Lip disorder	4	0
Oral disorder	14	0
Oral lichen planus	9	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
<i>Oral soft tissue haemorrhages</i>		
Lip haemorrhage	3	0
Mouth haemorrhage	36	0
Oral blood blister	47	0
Oral purpura	2	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	9	0
<i>Oral soft tissue signs and symptoms</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Anaesthesia oral	9	0
Burning mouth syndrome	13	0
Coating in mouth	4	0
Hypoaesthesia oral	568	0
Lip discolouration	1	0
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	52	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	84	0
Oral mucosal blistering	28	0
Oral mucosal eruption	24	0
Oral mucosal erythema	4	0
Oral mucosal exfoliation	9	0
Oral mucosal roughening	3	0
Oral pain	319	0
Oral pruritus	20	0
Paraesthesia oral	772	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	9	0
Lip swelling	860	0
Mouth swelling	111	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	12	0
<i>Pancreatic disorders NEC</i>		
Pancreatic disorder	1	0
Pancreatic mass	1	0
Pancreatic steatosis	1	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	2	0
Peptic ulcer haemorrhage	2	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	6	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	3	0
<i>Salivary gland disorders NEC</i>		
Salivary gland calculus	3	0
Salivary gland pain	12	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	11	0
Salivary gland enlargement	5	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	59	0
Lip ulceration	15	0
Mouth ulceration	672	0
Stomatitis	96	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Tongue disorders</i>		
Glossitis	15	0
Plicated tongue	4	0
Tongue disorder	29	0
Tongue geographic	3	0
Tongue haemorrhage	2	0
Tongue ulceration	28	0
Trichoglossia	6	0
<i>Tongue signs and symptoms</i>		
Glossodynia	233	0
Scalloped tongue	4	0
Stiff tongue	4	0
Strawberry tongue	1	0
Swollen tongue	554	0
Tongue blistering	26	0
Tongue coated	34	0
Tongue discolouration	30	0
Tongue discomfort	44	0
Tongue dry	19	0
Tongue eruption	8	0
Tongue erythema	5	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	15	0
Tongue pruritus	3	0
Tongue rough	2	0
Tongue spasm	3	0
<i>Tooth missing</i>		
Tooth loss	5	0
Gastrointestinal disorders SOC TOTAL	72198	11

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	14	0
Administration site coldness	1	0
Administration site erythema	6	0
Administration site extravasation	2	0
Administration site haemorrhage	1	0
Administration site induration	1	0
Administration site mass	1	0
Administration site pain	40	0
Administration site rash	3	0
Administration site reaction	5	0
Administration site swelling	3	0
Administration site urticaria	5	0
Administration site warmth	1	0
Puncture site bruise	58	0
Puncture site haemorrhage	1	0
Puncture site pain	21	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	22	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site bruise	24	0
Application site burn	3	0
Application site coldness	1	0
Application site discharge	1	0
Application site discolouration	1	0
Application site erythema	27	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 pain	44	0
Application site pruritus	18	0
Application site rash	3	0
Application site reaction	1	0
Application site scar	1	0
Application site swelling	4	0
Application site vesicles	10	0
Application site warmth	2	0
Application site wound	1	0
Instillation site bruise	1	0
Instillation site discomfort	1	0
Instillation site pain	5	0
Instillation site pruritus	1	0
Instillation site warmth	12	0
<i>Asthenic conditions</i>		
Asthenia	4315	3
Chronic fatigue syndrome	114	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Decreased activity	8	0
Fatigue	45445	0
Malaise	11388	3
Sluggishness	23	0
Body temperature altered		
Hyperthermia	10	0
Hypothermia	51	0
Temperature regulation disorder	26	0
Complications associated with device NEC		
Complication of device removal	1	0
Injury associated with device	6	0
Medical device site joint pain	1	0
Phantom shocks	4	0
Death and sudden death		
Brain death	4	3
Death	258	258
Drowning	1	0
Sudden death	28	28
Sudden unexplained death in epilepsy	1	1
Febrile disorders		
Hyperpyrexia	40	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	52390	0
Feelings and sensations NEC		
Chills	41454	0
Early satiety	1	0
Feeling abnormal	2753	0
Feeling cold	4977	0
Feeling drunk	121	0
Feeling hot	2220	0
Feeling jittery	42	0
Feeling of body temperature change	905	0
Feeling of relaxation	1	0
Hangover	167	0
Hunger	73	0
Sensation of blood flow	14	0
Sensation of foreign body	42	0
Temperature intolerance	68	0
Thirst	1188	0
Thirst decreased	11	0
Fibrosis NEC		
Fibrosis	5	0
Gait disturbances		
Decreased gait velocity	3	0
Gait disturbance	346	0
Gait inability	169	0
Loss of control of legs	44	0
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	211	0
Crepitations	7	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Crying	251	0
Deformity	1	0
Developmental delay	4	0
Discharge	6	0
Disease progression	1	0
Disease recurrence	1	0
Effusion	1	0
Energy increased	22	0
Exercise tolerance decreased	28	0
Foaming at mouth	4	0
General physical health deterioration	19	1
General symptom	10	0
Glassy eyes	6	0
High-pitched crying	5	0
Ill-defined disorder	5	0
Illness	4610	0
Induration	20	0
Influenza like illness	8982	1
Irritability postvaccinal	3	0
Local reaction	155	0
Moaning	8	0
Multiple organ dysfunction syndrome	16	7
Nonspecific reaction	3	0
Organ failure	1	0
Perforation	1	0
Peripheral swelling	5165	0
Pre-existing condition improved	13	0
Premature ageing	1	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	28	0
Sensitivity to weather change	1	0
Stenosis	1	0
Swelling	2426	0
Swelling face	925	0
Symptom recurrence	4	0
Tissue discolouration	1	0
Tissue infiltration	1	0
Unevaluable event	2	0
Healing abnormal NEC		
Impaired healing	2	0
Hernias NEC		
Hernia	3	0
Implant and catheter site reactions		
Catheter site urticaria	1	0
Implant site coldness	1	0
Implant site discharge	1	0
Implant site discolouration	3	0
Implant site hypoaesthesia	2	0
Implant site pain	4	0
Implant site rash	1	0
Implant site swelling	3	0
Implant site urticaria	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site vesicles	1	0
Implant site warmth	7	0
Inflamations		
Granuloma	1	0
Inflammation	629	0
Systemic inflammatory response syndrome	3	0
Infusion site reactions		
Infusion site bruising	1	0
Infusion site erythema	2	0
Infusion site mass	3	0
Infusion site nodule	2	0
Infusion site pain	12	0
Infusion site urticaria	1	0
Infusion site warmth	6	0
Injection site reactions		
Injected limb mobility decreased	36	0
Injection site atrophy	9	0
Injection site bruising	106	0
Injection site coldness	5	0
Injection site cyst	4	0
Injection site deformation	1	0
Injection site discharge	1	0
Injection site discolouration	7	0
Injection site discomfort	18	0
Injection site dryness	1	0
Injection site erythema	555	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	2	0
Injection site haemorrhage	15	0
Injection site hypersensitivity	4	0
Injection site hypoaesthesia	14	0
Injection site indentation	15	0
Injection site induration	8	0
Injection site inflammation	59	0
Injection site injury	4	0
Injection site irritation	4	0
Injection site joint discomfort	1	0
Injection site joint erythema	8	0
Injection site joint pain	34	0
Injection site joint swelling	1	0
Injection site mass	1343	0
Injection site movement impairment	5	0
Injection site muscle weakness	1	0
Injection site necrosis	5	0
Injection site nodule	4	0
Injection site oedema	26	0
Injection site pain	4239	0
Injection site papule	2	0
Injection site paraesthesia	24	0
Injection site pruritus	279	0
Injection site rash	289	0
Injection site reaction	117	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site scab	4	0
Injection site scar	7	0
Injection site swelling	231	0
Injection site thrombosis	1	0
Injection site ulcer	1	0
Injection site urticaria	37	0
Injection site vesicles	11	0
Injection site warmth	339	0
Interactions		
Drug interaction	30	0
Food interaction	1	0
Inhibitory drug interaction	11	0
Mass conditions NEC		
Cyst	20	0
Mass	70	0
Nodule	16	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	5	0
Mucosal inflammation	9	0
Mucosal pain	2	0
Mucosal ulceration	1	0
Oedema mucosal	3	0
Polyp	3	0
Necrosis NEC		
Fat necrosis	2	0
Necrosis	7	0
Oedema NEC		
Face oedema	29	0
Localised oedema	10	0
Oedema	60	0
Oedema peripheral	122	0
Pain and discomfort NEC		
Axillary pain	689	0
Chest discomfort	1823	0
Chest pain	4484	1
Discomfort	492	0
Facial discomfort	20	0
Facial pain	240	0
Hernia pain	2	0
Inflammatory pain	19	0
Non-cardiac chest pain	36	0
Pain	15059	0
Suprapubic pain	1	0
Tenderness	1754	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	87	0
Adverse event	24	0
Adverse reaction	48	0
Diet failure	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Drug ineffective	142	0
Drug intolerance	5	0
Idiosyncratic drug reaction	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	25	0
No reaction on previous exposure to drug	60	0
Remission not achieved	1	0
Similar reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	3	0
Therapeutic product effect incomplete	1	0
Therapeutic product effect prolonged	1	0
Therapeutic product ineffective	3	0
Therapeutic reaction time decreased	1	0
Therapeutic response decreased	1	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	117	0
Therapy non-responder	3	0
Treatment failure	6	0
Vaccination failure	26	0
Vaccine positive rechallenge	1	0
Trophic disorders		
Atrophy	3	0
Calcinosis	2	0
Dysplasia	2	0
Hyperplasia	1	0
Ulcers NEC		
Ulcer	38	0
Ulcer haemorrhage	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	17	0
Shoulder injury related to vaccine administration	38	0
Vaccination site atrophy	1	0
Vaccination site bruising	125	0
Vaccination site coldness	1	0
Vaccination site cyst	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	10	0
Vaccination site discomfort	43	0
Vaccination site dryness	1	0
Vaccination site erythema	662	0
Vaccination site extravasation	1	0
Vaccination site granuloma	8	0
Vaccination site haemorrhage	7	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	3	0
Vaccination site hypoaesthesia	24	0
Vaccination site induration	67	0
Vaccination site inflammation	48	0
Vaccination site injury	3	0
Vaccination site irritation	13	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	4	0
Vaccination site joint inflammation	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint movement impairment	11	0
Vaccination site joint pain	45	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	502	0
Vaccination site movement impairment	68	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	1880	0
Vaccination site papule	3	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	102	0
Vaccination site rash	170	0
Vaccination site reaction	23	0
Vaccination site scab	1	0
Vaccination site scar	5	0
Vaccination site swelling	462	0
Vaccination site urticaria	11	0
Vaccination site vesicles	9	0
Vaccination site warmth	362	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	80	0
General disorders SOC TOTAL	231110	306

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	27	0
Cholangitis	4	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	11	0
Cholelithiasis	11	0
<i>Cholestasis and jaundice</i>		
Cholestasis	5	0
Jaundice	44	0
Jaundice cholestatic	9	0
Ocular icterus	1	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
Gallbladder oedema	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	13	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	9	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Hepatic failure	4	0
Subacute hepatic failure	2	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	6	0
<i>Hepatic vascular disorders</i>		
Budd-Chiari syndrome	1	1
Hepatic artery thrombosis	1	0
Hepatic haemorrhage	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	0
Hepatic vein thrombosis	11	0
Portal hypertension	2	0
Portal vein phlebitis	1	0
Portal vein thrombosis	54	5
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	55	0
Hepatomegaly	3	0
Liver tenderness	6	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic necrosis	1	0
Hepatic steatosis	6	0
Hepatitis	21	0
Hepatitis acute	6	1
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0
Liver injury	18	0
Reye's syndrome	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	3	0
Hepatic disorders SOC TOTAL	351	8

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	23	0
<i>Allergic conditions NEC</i>		
Allergic oedema	19	0
Allergy to animal	1	0
Allergy to arthropod sting	2	0
Allergy to metals	1	0
Allergy to sting	1	0
Allergy to venom	1	0
Dust allergy	2	0
Hypersensitivity	1244	0
Infusion related hypersensitivity reaction	5	0
Mite allergy	2	0
Multiple allergies	14	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	5	0
Type IV hypersensitivity reaction	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	2	0
Allergy to chemicals	7	0
Allergy to vaccine	54	0
Contrast media reaction	4	0
Drug hypersensitivity	59	0
Food allergy	23	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	13	0
Reaction to preservatives	14	0
Rubber sensitivity	1	0
Smoke sensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	611	2
Anaphylactic shock	105	0
Anaphylactoid reaction	21	0
Anaphylactoid shock	3	0
<i>Atopic disorders</i>		
Atopy	2	0
Seasonal allergy	78	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	36	0
<i>Endocrine autoimmune disorders</i>		
Hashitoxicosis	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	33	0
Cytokine release syndrome	1	0
Cytokine storm	4	0
Haemophagocytic lymphohistiocytosis	7	0
Immune system disorder	19	0
Immune-mediated adverse reaction	8	0
Immunisation reaction	1	0
Pre-engraftment immune reaction	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Sensitisation	29	0
Immunodeficiency disorders NEC		
Immunodeficiency	4	0
Immunosuppression	5	0
Transplant rejections		
Corneal graft rejection	2	0
Transplant rejection	7	0
Vasculitides		
Eosinophilic granulomatosis with polyangiitis	1	0
Immune system disorders SOC TOTAL	2514	2

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
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	27	0
Appendicitis perforated	3	0
Diarrhoea infectious	3	0
Diverticulitis	23	0
Dysentery	4	0
Gastroenteritis	33	0
Gastrointestinal infection	5	0
Large intestine infection	2	0
Peritonitis	2	0
<i>Bacillary infections</i>		
Bacillus infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	4	0
Bacterial infection	27	1
Bacterial vaginosis	2	0
Cellulitis	470	1
Cellulitis orbital	1	0
Ear infection bacterial	2	0
Endocarditis bacterial	2	0
Eye infection bacterial	1	0
Folliculitis	9	0
Gangrene	1	0
Injection site cellulitis	7	0
Perichondritis	1	0
Periorbital cellulitis	4	0
Pneumonia bacterial	5	1
Post procedural cellulitis	1	0
Skin bacterial infection	5	0
Urinary tract infection bacterial	4	0
Vaccination site cellulitis	21	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	2	0
Bursitis infective	2	0
Intervertebral discitis	2	0
Osteomyelitis	1	0
<i>Bordetella infections</i>		
Pertussis	3	0
<i>Borrelial infections</i>		
Erythema migrans	2	0
Lyme disease	8	0
Relapsing fever	1	0
<i>Breast infections</i>		
Mastitis	33	0
<i>Brucella infections</i>		
Brucellosis	1	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Campylobacter infections</i>		
Campylobacter colitis	1	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Balanitis candida	1	0
Candida infection	60	0
Oral candidiasis	45	0
Skin candida	2	0
Vulvovaginal candidiasis	46	0
<i>Cardiac infections</i>		
Endocarditis	3	0
<i>Central nervous system and spinal infections</i>		
Cavernous sinus thrombosis	6	0
Central nervous system infection	1	0
Encephalitis	32	0
Encephalomyelitis	2	0
Extradural abscess	1	0
Meningitis	24	0
Myelitis	12	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	431	23
COVID-19 pneumonia	25	7
Coronavirus infection	4	0
Post-acute COVID-19 syndrome	4	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	36	0
<i>Corynebacteria infections</i>		
Diphtheria	2	0
<i>Coxiella infections</i>		
Q fever	108	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	3	0
Gingival abscess	7	0
Gingivitis	24	0
Lip infection	1	0
Oral infection	1	0
Oral pustule	3	0
Parotitis	11	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	1	0
Sialoadenitis	2	0

Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Tongue abscess	3	0
Tooth abscess	13	0
Tooth infection	11	0
Ear infections		
Ear infection	97	0
Labyrinthitis	135	0
Mastoiditis	3	0
Otitis externa	4	0
Otitis media	14	0
Otosalpingitis	1	0
Ectoparasitic infestations		
Acarodermatitis	6	0
Infestation	1	0
Trombidiasis	2	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	2	0
Infectious mononucleosis	46	0
Escherichia infections		
Escherichia infection	2	0
Escherichia sepsis	2	0
Eye and eyelid infections		
Conjunctivitis	68	0
Eye infection	25	0
Eyelid boil	3	0
Eyelid infection	3	0
Hordeolum	30	0
Keratouveitis	1	0
Retinitis	2	0
Female reproductive tract infections		
Endometritis	1	0
Pelvic inflammatory disease	1	0
Pyometra	1	1
Vaginal abscess	1	0
Vaginal infection	4	0
Flaviviral infections		
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1	0
Fungal infections NEC		
Ear infection fungal	1	0
Fungal infection	16	0
Fungal skin infection	9	0
Oral fungal infection	1	0
Overgrowth fungal	1	0
Severe asthma with fungal sensitisation	4	0
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	3	0
Hepatitis virus infections		
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	5	1
Herpes viral infections		
Eczema herpeticum	3	0
Genital herpes	55	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Genital herpes simplex	1	0
Haemorrhagic varicella syndrome	1	0
Herpes dermatitis	2	0
Herpes ophthalmic	14	0
Herpes simplex	36	0
Herpes simplex reactivation	2	0
Herpes virus infection	13	0
Herpes zoster	1219	0
Herpes zoster oticus	11	0
Herpes zoster reactivation	2	0
Meningoencephalitis herpetic	1	0
Nasal herpes	15	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	9	0
Oral herpes	632	0
Varicella	32	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	33	0
Abscess limb	20	0
Abscess soft tissue	2	0
Catheter site infection	1	0
Coinfection	1	0
Device related infection	1	0
Genital abscess	1	0
Groin infection	1	0
Infected bite	2	0
Infected cyst	3	0
Infection	423	3
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	17	0
Localised infection	97	0
Lymph gland infection	3	0
Lymph node abscess	1	0
Omphalitis	1	0
Pathogen resistance	3	0
Pyuria	1	0
Respiratory tract infection	6	0
Toxic shock syndrome	1	0
Vaccination site abscess	4	0
Vaccination site infection	22	0
Vestibulitis	3	0
Wound abscess	1	0
Infectious disorders carrier		
SARS-CoV-2 carrier	1	0
Infectious transmissions		
Secondary transmission	12	0
Vaccine virus shedding	1	0
Influenza viral infections		
H1N1 influenza	1	0
H2N2 influenza	2	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Influenza	6351	0
<i>Klebsiella infections</i>		
Pneumonia klebsiella	1	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	2	0
Bronchitis	20	0
Infectious pleural effusion	4	0
Infective exacerbation of bronchiectasis	1	0
Infective pulmonary exacerbation of cystic fibrosis	1	1
Lower respiratory tract infection	237	3
Pleural infection	1	0
Pneumonia	198	20
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	5	0
Orchitis	2	0
<i>Mumps viral infections</i>		
Mumps	9	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	2	0
Soft tissue infection	5	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>Polyomavirus infections</i>		
Progressive multifocal leukoencephalopathy	2	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	4	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	2	0
HIV-associated neurocognitive disorder	1	0
<i>Rotaviral infections</i>		
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	80	8

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	9	0
Septic shock	5	2
Urosepsis	7	1
Viraemia	3	0
<i>Skin structures and soft tissue infections</i>		
Carbuncle	1	0
Dermatitis infected	10	0
Eczema infected	1	0
Impetigo	7	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	16	0
Rash pustular	17	0
Skin infection	60	0
Subcutaneous abscess	8	0
Vaccination site pustule	5	0
<i>Staphylococcal infections</i>		
Furuncle	44	0
Staphylococcal bacteraemia	2	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	3	1
Toxic shock syndrome staphylococcal	2	0
Vulvovaginitis staphylococcal	1	0
<i>Streptococcal infections</i>		
Cellulitis streptococcal	1	0
Erysipelas	1	0
Meningitis pneumococcal	1	1
Pharyngitis streptococcal	8	0
Scarlet fever	1	0
Streptococcal infection	2	0
Tonsillitis streptococcal	1	0
<i>Tinea infections</i>		
Body tinea	3	0
Tinea cruris	1	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	1	0
<i>Treponema infections</i>		
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	4	0
Chronic sinusitis	13	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	25	0
Nasal vestibulitis	1	0
Nasopharyngitis	1643	0
Pharyngeal abscess	1	0
Pharyngitis	30	0
Rhinitis	44	0
Sinobronchitis	1	0
Sinusitis	312	0
Tonsillitis	69	0
Tracheitis	1	0
Upper respiratory tract infection	8	0
Urinary tract infections		
Cystitis	80	0
Genitourinary tract infection	1	0
Kidney infection	44	0
Pyelonephritis	4	0
Pyelonephritis acute	1	0
Pyelonephritis chronic	1	0
Renal abscess	1	0
Urinary tract infection	188	0
Vascular infections		
Haematoma infection	2	0
Infected lymphocele	1	0
Infected varicose vein	1	0
Lymphangitis	6	0
Viral infections NEC		
Arthritis viral	2	0
Bronchitis viral	1	0
Ear infection viral	1	0
Encephalitis viral	7	0
Eye infection viral	1	0
Gastritis viral	1	0
Gastroenteritis viral	65	0
Gastrointestinal viral infection	1	0
Hepatitis viral	2	0
Meningitis viral	16	0
Pleurisy viral	1	0
Pneumonia viral	6	1
Post viral fatigue syndrome	101	0
Sweating fever	715	0
Vestibular neuronitis	27	0
Viral diarrhoea	4	0
Viral infection	61	0
Viral labyrinthitis	6	0
Viral myocarditis	2	0
Viral pericarditis	2	0
Viral pharyngitis	29	0
Viral rash	72	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Infections SOC TOTAL	15726	76

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Abdomen crushing	3	0
Colon injury	1	0
Lip injury	2	0
Mouth injury	1	0
Oral contusion	11	0
Palate injury	1	0
Splenic rupture	4	0
Tongue injury	3	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	16	0
<i>Anaesthetic and allied procedural complications</i>		
Anaesthetic complication	3	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	4	0
Sedation complication	3	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	7	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
Vasoplegia syndrome	1	0
<i>Cardiovascular injuries</i>		
Heart injury	4	0
Vascular injury	4	0
<i>Cerebral injuries NEC</i>		
Brain contusion	12	0
Brain herniation	4	0
Concussion	7	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	1
Subdural haemorrhage	4	0
<i>Chemical injuries</i>		
Chemical burn	1	0
Chemical burn of oral cavity	2	0
Chemical burn of skin	4	0
Chemical phlebitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Chest crushing	11	0
Chest injury	1	0
Foreign body in throat	1	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	65	0
Frostbite	1	0
Cranial nerve injuries		
Cranial nerve injury	1	0
Optic nerve injury	2	0
Vth nerve injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	9	0
Exposure via breast milk	43	0
Foetal exposure during pregnancy	41	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	1089	0
Maternal exposure during pregnancy	236	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	3	0
Paternal exposure during pregnancy	15	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to household chemicals	1	0
Exposure to toxic agent	1	0
Exposure to vaccinated person	1	0
Eye injuries NEC		
Cataract traumatic	1	0
Eye contusion	48	0
Eye injury	28	0
Eyelid contusion	4	0
Foreign body in eye	1	0
Hyphaema	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Periorbital haemorrhage	1	0
Retinal injury	3	0
Superficial injury of eye	1	0
Fractures and dislocations NEC		
Fracture	1	0
Joint dislocation	9	0
Multiple fractures	1	0
Stress fracture	4	0
Gastrointestinal and hepatobiliary procedural complications		
Peripancreatic fluid collection	1	0
Procedural nausea	24	0
Procedural vomiting	7	0
Heat injuries (excl thermal burns)		
Heat cramps	1	0
Heat exhaustion	4	0
Heat illness	4	0
Heat oedema	13	0

Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021
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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Heat stroke	7	0
Intentional product misuses		
Intentional product misuse	6	0
Intentional product use issues		
Intentional product use issue	1	0
Limb fractures and dislocations		
Ankle fracture	3	0
Atypical femur fracture	1	0
Clavicle fracture	16	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	1	0
Wrist fracture	2	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	6	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	61	0
Prescription drug used without a prescription	1	0
Product use issue	4	0
Vaccination error	7	0
Wrong device used	1	0
Wrong drug	5	0
Wrong schedule	1	0
Wrong technique in product usage process	7	0
Muscle, tendon and ligament injuries		
Epicondylitis	17	0
Ligament injury	3	0
Ligament rupture	1	0
Ligament sprain	17	0
Muscle injury	33	0
Muscle rupture	15	0
Muscle strain	41	0
Post-traumatic neck syndrome	3	0
Repetitive strain injury	2	0
Tendon injury	4	0
Tendon rupture	13	0
Nerve injuries NEC		
Nerve injury	94	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	8	0
Procedural dizziness	31	0
Non-occupational environmental exposures		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Exposure to noise	2	0
Non-site specific injuries NEC		
Animal bite	1	0
Arthropod bite	4	0
Arthropod sting	11	0
Bite	1	0
Electric shock	27	0
Fall	212	1
Inflammation of wound	3	0
Injury	11	0
Internal injury	1	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Road traffic accident	2	0
Soft tissue injury	3	0
Tissue injury	1	0
Traumatic haematoma	3	0
Traumatic shock	1	0
Wound	7	0
Wound complication	12	0
Wound haemorrhage	10	0
Wound secretion	2	0
Non-site specific procedural complications		
Administration related reaction	2	0
Incision site erythema	1	0
Incision site haemorrhage	1	0
Incision site oedema	1	0
Incision site pain	9	0
Infusion related reaction	20	0
Injection related reaction	599	0
Needle fatigue	1	0
Post procedural complication	35	0
Post procedural contusion	2	0
Post procedural haematoma	1	0
Procedural hypertension	1	0
Procedural pain	7	0
Procedural site reaction	1	0
Suture related complication	1	0
Occupational exposures		
Occupational exposure to product	1	0
Off label uses		
Off label use	18	0
Overdoses NEC		
Intentional overdose	7	0
Overdose	20	0
Prescribed overdose	1	0
Pathways and sources of exposure		
Exposure via body fluid	1	0
Exposure via unknown route	1	0
Peripheral nerve injuries		
Brachial plexus injury	2	0
Median nerve injury	2	0
Sciatic nerve injury	1	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Ulnar nerve injury	2	0
Poisoning and toxicity		
Alcohol poisoning	3	0
Chemical poisoning	1	0
Metal poisoning	1	0
Poisoning	5	0
Systemic toxicity	1	0
Toxicity to various agents	9	0
Product administration errors and issues		
Accidental overdose	3	0
Accidental underdose	1	0
Contraindicated product administered	4	0
Duplicate therapy error	2	0
Expired product administered	24	0
Extra dose administered	6	0
Inappropriate schedule of product administration	20	0
Incomplete course of vaccination	2	0
Incorrect dose administered	6	0
Incorrect product administration duration	1	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	31	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	15	0
Product administered to patient of inappropriate age	17	0
Product administration error	16	0
Product dose omission issue	3	0
Wrong patient received product	1	0
Wrong product administered	16	0
Product confusion errors and issues		
Product label confusion	1	0
Product name confusion	2	0
Product dispensing errors and issues		
Product dispensing error	14	0
Product monitoring errors and issues		
Documented hypersensitivity to administered product	1	0
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	9	0
Product prescribing error	3	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	5	0
Product transcribing errors and communication issues		
Product communication issue	1	0
Radiation injuries		
Sunburn	44	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Kidney rupture	1	0
Reproductive system and breast injuries		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Penile contusion	2	0
Uterine rupture	1	0
Reproductive tract and breast procedural complications		
Postmastectomy lymphoedema syndrome	1	0
Respiratory tract and thoracic cavity procedural complications		
Pulmonary oil microembolism	2	0
Site specific injuries NEC		
Back injury	7	0
Central nervous system injury	1	0
Face crushing	1	0
Face injury	2	0
Head injury	34	0
Limb crushing injury	8	0
Limb injury	211	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	2619	0
Nail injury	1	0
Scar	22	0
Scratch	4	0
Skin abrasion	5	0
Skin injury	15	0
Skin laceration	1	0
Skin pressure mark	1	0
Skin wound	6	0
Subcutaneous haematoma	1	0
Skin procedural complications		
Recall phenomenon	1	0
Spinal cord injuries NEC		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury	1	0
Spinal cord injury sacral	1	0
Spinal fractures and dislocations		
Spinal compression fracture	3	0
Spinal fracture	5	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
Stoma site haemorrhage	1	0
Stoma site pain	2	0
Stoma site rash	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	4	0
Burn oral cavity	10	0
Burns second degree	8	0
Cold burn	3	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Thermal burn	46	0
Thermal burns of eye	43	0
<i>Transplantation complications</i>		
Transplant failure	1	0
<i>Underdoses NEC</i>		
Intentional underdose	1	0
Underdose	6	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	4	0
Post vaccination syndrome	1	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	92	0
Injuries SOC TOTAL	6788	2

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Blood cortisol	1	0
Cortisol decreased	1	0
Cortisol increased	1	0
<i>Adrenal medulla tests</i>		
Epinephrine increased	1	0
Norepinephrine increased	2	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	6	0
Audiogram	1	0
<i>Autoimmunity analyses</i>		
Antimitochondrial antibody positive	1	0
Antineutrophil cytoplasmic antibody	1	0
Antinuclear antibody positive	1	0
Antiphospholipid antibodies	2	0
Antiphospholipid antibodies positive	1	0
Cold agglutinins positive	1	0
DNA antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	4	0
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test	1	0
Staphylococcus test positive	1	0
<i>Blood counts NEC</i>		
Blood count	9	0
Blood count abnormal	3	0
Full blood count	8	0
Full blood count abnormal	2	0
Full blood count decreased	2	0
Full blood count increased	1	0
<i>Blood gas and acid base analyses</i>		
Blood gases	1	0
Blood lactic acid	2	0
Blood lactic acid increased	5	0
Blood pH	14	0
Blood pH increased	13	0
Carbon dioxide increased	1	0
Oxygen consumption	1	0
Oxygen saturation	23	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	172	2
<i>Blood grouping and cross-matching analyses</i>		
Blood group O	2	0
Blood grouping	1	0
Rhesus antigen negative	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Scan lymph nodes	2	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	19	0
Blood glucose abnormal	17	0
Blood glucose decreased	35	0
Blood glucose fluctuation	29	0
Blood glucose increased	172	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Glycosylated haemoglobin increased	2	0
Cardiac auscultatory investigations		
Cardiac murmur	23	0
Heart sounds	16	0
Heart sounds abnormal	7	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	2	0
Myocardial strain	16	0
Stroke volume decreased	2	0
Venous pressure jugular increased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
Prostatic specific antigen	1	0
Prostatic specific antigen increased	2	0
Central nervous system histopathology procedures		
Biopsy brain	1	0
Central nervous system imaging procedures		
Computerised tomogram head	17	0
Magnetic resonance imaging head	39	0
Scan brain	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	4	0
CSF white blood cell count increased	1	0
Chemistry analyses NEC		
Histamine abnormal	2	0
Histamine level	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	6	0
Cholesterol analyses		
Blood cholesterol increased	7	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	118	0
Bleeding time	5	0
Bleeding time abnormal	3	0
Bleeding time prolonged	4	0
Blood fibrinogen decreased	7	0
Blood fibrinogen increased	2	0
Blood thromboplastin	1	0
Blood thromboplastin abnormal	2	0
Clot retraction	1	0
Coagulation factor	1	0
Coagulation factor VIII level decreased	4	0
Coagulation time	7	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Coagulation time prolonged	11	0
Coagulation time shortened	3	0
Fibrin D dimer	1	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	39	0
International normalised ratio	2	0
International normalised ratio abnormal	10	0
International normalised ratio decreased	39	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	82	0
Prothrombin level increased	1	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
Lipase increased	1	0
Pancreatic enzymes increased	1	0
<i>ECG investigations</i>		
Cardiac telemetry	1	0
Electrocardiogram	5	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	2	0
Electrocardiogram ST-T segment abnormal	7	0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	15	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	26	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin	1	0
Faecal calprotectin increased	7	0
Stool analysis abnormal	1	0
<i>Fertility analyses</i>		
Semen volume decreased	2	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate	1	0
<i>Fungus identification and serology</i>		
Fungal test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Computerised tomogram abdomen	4	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood insulin increased	3	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	2	0
Haematology test abnormal	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate	1	0
Red blood cell sedimentation rate increased	6	0
Heart rate and pulse investigations		
Brachial pulse decreased	1	0
Heart rate	983	0
Heart rate abnormal	48	0
Heart rate decreased	106	0
Heart rate increased	1883	0
Heart rate irregular	163	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	6	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	24	0
Pulse absent	4	0
Pulse pressure abnormal	1	0
Pulse pressure increased	3	0
Pulse waveform abnormal	1	0
Sinus rhythm	5	0
Histopathology procedures NEC		
Smear test	2	0
Imaging procedures NEC		
Computerised tomogram	7	0
Computerised tomogram normal	1	0
Magnetic resonance imaging	1	0
Scan	1	0
X-ray	1	0
Immunoglobulin analyses		
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	2	0
Antibody test abnormal	1	0
Antibody test negative	5	0
Immunology test	6	0
Immunology test normal	1	0
Mast cell degranulation present	1	0
Immunology skin tests NEC		
Allergy alert test	2	0
Skin test positive	4	0
Investigations NEC		
APACHE II score	1	0
Blood test	41	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood test abnormal	51	0
Laboratory test	1	0
Polymerase chain reaction positive	2	0
Quality of life decreased	1	0
Liver function analyses		
Alanine aminotransferase increased	17	0
Aspartate aminotransferase increased	3	0
Bile output	3	0
Blood bilirubin	1	0
Blood bilirubin increased	3	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	12	0
Liver function test	3	0
Liver function test abnormal	33	0
Liver function test increased	6	0
Transaminases increased	9	0
Metabolism tests NEC		
Blood ketone body	9	0
Blood uric acid increased	1	0
Ubiquinone	4	0
Ubiquinone decreased	2	0
Urine ketone body present	2	0
Microbiology and serology tests NEC		
Blood culture	2	0
Blood culture negative	1	0
Septic screen	1	0
Mineral and electrolyte analyses		
Blood calcium	1	0
Blood calcium increased	1	0
Blood cyanide	1	0
Blood iron	10	0
Blood iron decreased	9	0
Blood iron increased	1	0
Blood magnesium decreased	2	0
Blood phosphorus abnormal	1	0
Blood phosphorus decreased	5	0
Blood phosphorus increased	2	0
Blood potassium decreased	7	0
Blood potassium increased	7	0
Blood sodium	2	0
Blood sodium decreased	4	0
Serum ferritin	1	0
Serum ferritin decreased	2	0
Serum ferritin increased	2	0
Sweat test	2	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone densitometry	1	0
Skull X-ray	8	0
X-ray of pelvis and hip	1	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Swollen joint count increased	2	0
Tender joint count	3	0
<i>Mycobacteria identification and serology</i>		
Interferon gamma release assay positive	2	0
Tuberculin test	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	15	0
Electromyogram abnormal	1	0
Joint position sense decreased	1	0
Lumbar puncture	12	0
Sensory level abnormal	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	2	0
Intraocular pressure increased	3	0
Intraocular pressure test	8	0
Visual tracking test	1	0
<i>Physical examination procedures and organ system status</i>		
Body height decreased	1	0
Body surface area	2	0
Body temperature	983	0
Body temperature abnormal	76	0
Body temperature decreased	129	0
Body temperature fluctuation	172	0
Body temperature increased	1071	0
Body temperature normal	3	0
Breath sounds	1	0
Breath sounds abnormal	5	0
Dermatologic examination abnormal	1	0
General physical condition abnormal	4	0
Grip strength	7	0
Grip strength decreased	30	0
Head lag	17	0
Lymph node palpable	5	0
Male genital examination abnormal	1	0
Menstruation normal	2	0
Muscle strength abnormal	3	0
Neurological examination	1	0
Neurological examination normal	1	0
Ophthalmological examination	1	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Psoriasis area severity index decreased	1	0
Respiratory rate	10	0
Respiratory rate decreased	24	0
Respiratory rate increased	76	0
Skin temperature	170	0
Temperature difference of extremities	6	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	148	0
Weight increased	33	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood prolactin increased	1	0
Blood thyroid stimulating hormone	1	0
Blood thyroid stimulating hormone decreased	3	0
Blood thyroid stimulating hormone increased	4	0
Platelet analyses		
Platelet count	2	0
Platelet count abnormal	1	0
Platelet count decreased	251	0
Platelet count increased	5	0
Platelet count normal	1	0
Plateletcrit	1	0
Protein analyses NEC		
C-reactive protein abnormal	2	0
C-reactive protein increased	18	0
Protein total	2	0
Protein total increased	1	0
Red blood cell analyses		
Haematocrit	9	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin	5	0
Haemoglobin decreased	12	0
Haemoglobin increased	1	0
Mean cell haemoglobin concentration	1	0
Mean cell volume abnormal	2	0
Red blood cell count	1	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	6	0
Blood urea increased	1	0
Glomerular filtration rate decreased	2	0
Reproductive hormone analyses		
17 ketosteroids urine decreased	1	0
Anti-Muellerian hormone level decreased	2	0
Blood oestrogen increased	1	0
Dihydrotestosterone decreased	1	0
False negative pregnancy test	2	0
Human chorionic gonadotropin decreased	1	0
Pregnancy test	12	0
Pregnancy test false positive	1	0
Pregnancy test negative	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	1	0
Reproductive organ and breast imaging procedures		
Mammogram	1	0
Ultrasound scan vagina normal	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	12	0
Forced expiratory volume normal	1	0
Forced vital capacity decreased	1	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	3	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	16	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	6	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	1	0
Troponin	2	0
Troponin I increased	1	0
Troponin T	1	0
Troponin T increased	1	0
Special sense investigations NEC		
Olfactory test	1	0
Therapeutic drug monitoring analyses		
Analgesic drug level	17	0
Analgesic drug level increased	1	0
Analgesic drug level therapeutic	1	0
Anticoagulation drug level above therapeutic	3	0
Anticoagulation drug level below therapeutic	3	0
Anticoagulation drug level increased	1	0
Antidepressant drug level decreased	1	0
Drug level increased	1	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0
Thyroxine	1	0
Thyroxine abnormal	1	0
Tri-iodothyronine decreased	7	0
Tissue enzyme analyses NEC		
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Lactate dehydrogenase urine increased	1	0
Toxicology laboratory analyses		
Blood aluminium	1	0
Blood cannabinoids	1	0
Blood carbon monoxide increased	2	0
Blood heavy metal test	1	0
Blood lead	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Drug screen positive	3	0
Urinalysis NEC		
Blood urine	30	0
Blood urine present	67	0
Cells in urine	2	0
Crystal urine	3	0
Medication crystals in urine present	1	0
Protein urine	2	0
Protein urine present	1	0
Red blood cells urine	1	0
Urea urine increased	1	0
Urine analysis	1	0
Urine analysis abnormal	13	0
Urine analysis normal	3	0
White blood cells urine positive	1	0
pH urine	8	0
pH urine decreased	2	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	43	0
Urine output decreased	18	0
Urine output increased	10	0
Urinary tract imaging procedures		
Cystoscopy	2	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	4	0
Blood pressure ambulatory decreased	1	0
Blood pressure decreased	78	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure increased	269	0
Blood pressure measurement	91	0
Blood pressure normal	5	0
Blood pressure systolic	1	0
Blood pressure systolic increased	5	0
Capillary nail refill test	1	0
Virus identification and serology		
Coronavirus test	38	0
Cytomegalovirus test	1	0
HIV antibody negative	2	0
Hepatitis B core antibody positive	1	0
Herpes virus test	1	0
Human papilloma virus test positive	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	6	0
SARS-CoV-2 antibody test negative	16	0
SARS-CoV-2 antibody test positive	3	0

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Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
SARS-CoV-2 test	20	0
SARS-CoV-2 test false negative	4	0
SARS-CoV-2 test false positive	3	0
SARS-CoV-2 test negative	16	0
SARS-CoV-2 test positive	90	0
Viral test	4	0
Viral test positive	1	0
Vitamin analyses		
Blood folate	2	0
Blood folate decreased	4	0
Vitamin B12	1	0
Vitamin B12 decreased	2	0
Vitamin D decreased	3	0
Water and electrolyte analyses NEC		
Blood osmolarity	1	0
Volume blood	6	0
White blood cell analyses		
CD4 lymphocytes decreased	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	4	0
Lymphocyte count	1	0
Lymphocyte count decreased	5	0
Lymphocyte count increased	3	0
Mononuclear cell count abnormal	1	0
Neutrophil count	3	0
Neutrophil count decreased	13	0
Neutrophil count increased	2	0
Neutrophil toxic granulation present	1	0
White blood cell count	15	0
White blood cell count decreased	26	0
White blood cell count increased	8	0
Investigations SOC TOTAL	9273	2

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	37	0
Decreased appetite	6078	1
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	20	0
Food refusal	35	0
Hyperphagia	6	0
Hypophagia	27	0
Increased appetite	56	0
Salt craving	4	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	2	0
Hypocalcaemia	6	0
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	83	0
Diabetes mellitus inadequate control	28	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	18	0
Type 2 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	32	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	136	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	3	0
Fluid imbalance	1	0
Hyperosmolar state	1	1
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	6	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	8	0
Food intolerance	11	0
Gluten sensitivity	3	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	51	0
Abnormal weight gain	22	0
Cachexia	2	0
Feeding disorder	179	0
Food aversion	55	0
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0

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Report Run Date: 14-Jun-2021
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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Overweight	2	0
Poor feeding infant	10	0
Starvation	1	0
Underweight	1	0
Weight loss poor	2	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	126	0
Insulin resistance	8	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	2	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	93	0
Hypoglycaemia unawareness	3	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	9	0
Iron excess		
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Lipoedema	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	1	0
Ketosis	4	0
Lactic acidosis	2	0
Metabolic acidosis	9	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	3	0
Phosphorus metabolism disorders		
Hypophosphataemia	2	0
Potassium imbalance		
Hyperkalaemia	6	1
Hypokalaemia	4	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	2	0
Hyponatraemia	20	0
Hyponatraemic syndrome	3	1
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	6	0
Total fluid volume decreased		
Dehydration	622	0
Hypovolaemia	1	0
Total fluid volume increased		
Fluid overload	7	0
Fluid retention	58	1

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	1	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	4	0
Vitamin B12 deficiency	4	0
Metabolic disorders SOC TOTAL	7982	7

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Report Run Date: 14-Jun-2021
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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	385	0
Arthritis enteropathic	1	0
Arthropathy	27	0
Autoimmune arthritis	7	0
Haemarthrosis	7	0
Oligoarthritis	1	0
Palindromic rheumatism	3	0
Polyarthritis	14	0
Rheumatic fever	5	0
Sacroiliitis	3	0
<i>Bone disorders NEC</i>		
Bone disorder	3	0
Bone erosion	1	0
Bone loss	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	8	0
Osteitis	9	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	962	0
Bone swelling	5	0
Coccydynia	6	0
Pain in jaw	544	0
Pubic pain	1	0
Spinal pain	224	0
<i>Bursal disorders</i>		
Bursitis	113	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	58	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	2	0
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	62	0
Reynold's syndrome	6	0
Scleroderma	2	0
Sjogren's syndrome	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	1	0
Gouty tophus	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Finger deformity	3	0
Foot deformity	1	0
Hand deformity	3	0
Limb deformity	6	0
Wrist deformity	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Fractures NEC		
Osteoporotic fracture	2	0
Intervertebral disc disorders NEC		
Intervertebral disc degeneration	2	0
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Ankle impingement	1	0
Femoroacetabular impingement	2	0
Joint ankylosis	2	0
Joint contracture	1	0
Joint instability	2	0
Joint laxity	5	0
Joint lock	42	0
Ligament laxity	1	0
Patellofemoral pain syndrome	5	0
Periarthritis	261	0
Rotator cuff syndrome	55	0
Temporomandibular joint syndrome	16	0
Joint related signs and symptoms		
Arthralgia	20746	0
Jaw clicking	4	0
Joint effusion	5	0
Joint noise	40	0
Joint range of motion decreased	3	0
Joint stiffness	382	0
Joint swelling	748	0
Joint vibration	4	0
Joint warmth	30	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	30	0
Metabolic bone disorders		
Dwarfism	1	0
Osteopenia	2	0
Osteoporosis	10	0
Muscle infections and inflammations		
Myositis	31	0
Polymyositis	1	0
Muscle pains		
Fibromyalgia	234	0
Myalgia	25086	0
Myalgia intercostal	2	0
Myofascial pain syndrome	21	0
Muscle related signs and symptoms NEC		
Haematoma muscle	3	0
Muscle atrophy	22	0
Muscle discomfort	13	0
Muscle disorder	7	0
Muscle fatigue	874	0
Muscle haemorrhage	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Muscle mass	7	0
Muscle oedema	2	0
Muscle spasms	2642	0
Muscle swelling	27	0
Muscle tightness	173	0
Muscle twitching	437	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	51	0
Nuchal rigidity	15	0
Torticollis	8	0
Trismus	51	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1754	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Extremity contracture	2	0
Infantile back arching	1	0
Limb mass	12	0
Mandibular mass	1	0
Mastication disorder	4	0
Mobility decreased	97	0
Muscle contracture	2	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	2024	0
Posture abnormal	1	0
Somatic dysfunction	1	0
Weight bearing difficulty	6	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	3	0
Head deformity	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Connective tissue inflammation	2	0
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	8	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5210	0
Flank pain	69	0
Growing pains	8	0
Limb discomfort	2049	0
Musculoskeletal chest pain	375	0
Musculoskeletal discomfort	118	0
Musculoskeletal pain	63	0
Neck pain	2716	0
Pain in extremity	19401	0
Rheumatic disorder	16	0
<i>Myopathies</i>		
Compartment syndrome	3	0
Muscle necrosis	1	0
Myopathy	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Rhabdomyolysis	8	1
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	47	0
Spinal osteoarthritis	4	0
Psoriatic arthropathies		
Psoriatic arthropathy	24	0
Rheumatoid arthropathies		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	141	0
Rheumatoid nodule	1	0
Still's disease	5	0
Soft tissue disorders NEC		
Axillary mass	60	0
Clubbing	1	0
Fistula	2	0
Groin pain	186	0
Neck mass	19	0
Soft tissue disorder	1	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	27	0
Arthritis reactive	34	0
Axial spondyloarthritis	1	0
Spondylitis	4	0
Synovial disorders		
Synovial cyst	7	0
Synovitis	13	0
Tendon disorders		
Enthesopathy	1	0
Tendon discomfort	4	0
Tendon disorder	6	0
Tendon pain	31	0
Tendonitis	58	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	22	0
Muscle & tissue disorders SOC TOTAL	89313	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>Anal canal neoplasms malignant</i>		
Anal cancer	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	1	0
Follicular lymphoma	1	0
<i>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	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	40	0
Breast cancer in situ	1	0
Breast cancer male	2	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	3	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	2	0
Brain neoplasm malignant	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	3	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	2	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Gastrointestinal neoplasms benign NEC</i>		
Gastrointestinal tract adenoma	1	0
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Glial tumours malignant</i>		
Glioblastoma	1	0
Glioblastoma multiforme	1	0
<i>Haematologic neoplasms NEC</i>		
Systemic mastocytosis	1	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	3	0
<i>Hepatoblastomas</i>		
Hepatoblastoma	1	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	1	0
<i>Leiomyosarcomas</i>		
Pleomorphic leiomyosarcoma	1	0
<i>Leukaemias NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Leukaemia	1	0
Leukaemia recurrent	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	6	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms benign		
Papillary cystadenoma lymphomatosum	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer	1	0
Squamous cell carcinoma of the oral cavity	2	0
Lymphomas unspecified NEC		
Lymphoma	14	0
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Lymphoproliferative disorder	1	0
Lymphoproliferative disorder in remission	1	0
Mediastinal neoplasms malignancy unspecified NEC		
Good syndrome	1	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to central nervous system	1	1
Metastases to lung	1	1
Metastases to unknown and unspecified sites		
Metastasis	3	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	6	1
Squamous cell carcinoma	2	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm recurrence	6	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	2	0
Meningioma	3	0
Schwannoma	1	0
Neuromas		
Acoustic neuroma	3	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	1	0
Non-small cell neoplasms malignant of the respiratory tract cell type specified		
Lung adenocarcinoma	1	1
Ocular neoplasms benign		
Eye naevus	3	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oesophageal carcinoma	4	0
Oesophageal squamous cell carcinoma	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<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	8	0
Ovarian cancer recurrent	1	0
Ovarian cancer stage IV	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	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>Prostatic neoplasms malignant</i>		
Prostate cancer	7	0
Prostate cancer metastatic	1	0
<i>Renal neoplasms malignant</i>		
Clear cell renal cell carcinoma	3	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>		
Maxillofacial sinus neoplasm	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	5	0
Lung cancer metastatic	1	0
Lung neoplasm malignant	10	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
<i>Skin neoplasms benign</i>		
Acrochordon	3	0
Anogenital warts	2	0
Haemangioma of skin	14	0
Melanocytic naevus	3	0
Skin papilloma	15	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	5	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Knuckle pads	1	0
Lipoma	4	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	4	0
<i>Uterine neoplasms malignant NEC</i>		
Uterine cancer	2	0
<i>Vulval neoplasms malignant</i>		
Vulval cancer	1	0
Neoplasms SOC TOTAL	296	4

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	23	0
Extensor plantar response	2	0
Hyperreflexia	5	0
Hyporeflexia	16	0
Poor sucking reflex	3	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	23	0
<i>Absence seizures</i>		
Petit mal epilepsy	30	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	3	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	294	4
Miller Fisher syndrome	17	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Auditory nerve disorders</i>		
Acoustic neuritis	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	10	0
Horner's syndrome	2	0
Orthostatic intolerance	3	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	2	0
Brain stem infarction	2	2
Brain stem stroke	3	2
Carotid artery occlusion	3	0
Carotid artery thrombosis	9	1
Cerebellar haemorrhage	4	0
Cerebellar infarction	4	0
Cerebellar stroke	9	0
Cerebral artery embolism	8	0
Cerebral artery occlusion	3	0
Cerebral artery thrombosis	8	0
Cerebral haematoma	12	1
Cerebral haemorrhage	141	37
Cerebral infarction	73	3
Cerebral ischaemia	3	0
Cerebral thrombosis	33	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	912	36
Embolic stroke	19	0
Haemorrhage intracranial	46	8

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Haemorrhagic cerebral infarction	2	1
Haemorrhagic stroke	31	4
Haemorrhagic transformation stroke	7	3
Internal capsule infarction	1	0
Intracranial haematoma	7	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	2	0
Ischaemic stroke	108	3
Lacunar infarction	4	0
Lacunar stroke	19	0
Spinal cord haematoma	1	0
Spinal stroke	1	0
Subarachnoid haemorrhage	96	5
Thalamus haemorrhage	6	0
Thrombotic stroke	10	0
Vertebral artery occlusion	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	4	0
Central nervous system inflammation	10	0
Neurosarcoidosis	3	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	1
Carotid artery stenosis	2	0
Central nervous system vasculitis	3	0
Cerebral amyloid angiopathy	2	0
Cerebral congestion	3	0
Cerebral microhaemorrhage	1	0
Cerebral small vessel ischaemic disease	2	0
Cerebral vasoconstriction	2	0
Cerebrovascular disorder	3	0
Internal carotid artery deformity	1	0
Reversible cerebral vasoconstriction syndrome	3	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	180	20
Cerebral venous thrombosis	41	4
Superior sagittal sinus thrombosis	28	2
Transverse sinus thrombosis	5	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	5	0
Choreiform movements		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	7	0
Diabetic neuropathy	2	0
Polyneuropathy chronic	1	0
Coma states		
Coma	15	0
Diabetic coma	3	0
Hypoglycaemic coma	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Coordination and balance disturbances</i>		
Ataxia	30	0
Balance disorder	728	0
Cerebellar ataxia	1	0
Coordination abnormal	106	0
Dysdiadochokinesis	1	0
Dysstasia	94	0
Hand-eye coordination impaired	1	0
Nystagmus	19	0
<i>Cortical dysfunction NEC</i>		
Agraphia	1	0
Alexia	4	0
Aphasia	116	0
Apraxia	1	0
Dysgraphia	6	0
Dyslexia	2	0
Dyspraxia	4	0
Neurologic neglect syndrome	3	0
Visuospatial deficit	2	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Neurovascular conflict	1	0
Paresis cranial nerve	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	20	0
Dementia with Lewy bodies	1	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	4	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	8	0
Demyelination	15	0
Neuromyelitis optica spectrum disorder	2	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	13	0
Consciousness fluctuating	4	0
Depressed level of consciousness	78	0
Lethargy	4415	0
Loss of consciousness	936	0
Postictal state	1	0
Sedation	13	0
Somnolence	1718	1
Stupor	8	0
Syncope	2256	0
<i>Disturbances in sleep phase rhythm</i>		
Advanced sleep phase	1	0
Circadian rhythm sleep disorder	5	0
Delayed sleep phase	1	0
Irregular sleep phase	1	0
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ballismus	1	0
Bradykinesia	28	0
Clumsiness	42	0
Dyskinesia	100	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	12	0
Hyperkinesia	26	0
Hypokinesia	59	0
Meige's syndrome	1	0
Motor dysfunction	13	0
Movement disorder	76	0
Psychomotor hyperactivity	34	0
Tardive dyskinesia	1	0
Dystonias		
Dystonia	17	0
Dystonic tremor	3	0
Opisthotonus	4	0
Writer's cramp	1	0
Encephalitis NEC		
Limbic encephalitis	1	0
Noninfective encephalitis	4	0
Encephalopathies NEC		
Autoimmune encephalopathy	3	0
Encephalopathy	5	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	3	0
Encephalopathies toxic and metabolic		
Hepatic encephalopathy	2	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	6	0
Microvascular cranial nerve palsy	2	0
VIth nerve paralysis	8	0
Facial cranial nerve disorders		
Bell's palsy	414	0
Facial nerve disorder	5	0
Facial paralysis	239	0
Facial paresis	123	0
Facial spasm	28	0
Oculofacial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	74	0
Headaches NEC		
Cervicogenic headache	5	0
Cluster headache	646	0
Cold-stimulus headache	71	0
Drug withdrawal headache	15	0
Exertional headache	11	0
External compression headache	4	0
Headache	74935	4
Medication overuse headache	14	0
New daily persistent headache	18	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Occipital neuralgia	18	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	879	0
Tension headache	1343	0
Thunderclap headache	42	0
Vascular headache	69	0
Hydrocephalic conditions		
Hydrocephalus	11	0
Hypoglossal nerve disorders		
Tongue paralysis	5	0
Increased intracranial pressure disorders		
Brain compression	3	0
Brain oedema	22	1
Cerebrospinal fluid circulation disorder	3	0
Cytotoxic oedema	1	0
Idiopathic intracranial hypertension	6	0
Intracranial pressure increased	20	0
Intellectual disabilities		
Intellectual disability	9	0
Lumbar spinal cord and nerve root disorders		
Lumbar radiculopathy	2	0
Sciatica	159	0
Memory loss (excl dementia)		
Amnesia	263	0
Memory impairment	248	0
Transient global amnesia	17	0
Meningitis NEC		
Meningitis noninfective	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	144	1
Disturbance in attention	591	0
Judgement impaired	3	0
Mental impairment	108	0
Migraine headaches		
Basilar migraine	4	0
Hemiplegic migraine	34	0
Migraine	6584	0
Migraine with aura	314	0
Migraine without aura	42	0
Ophthalmic migraine	9	0
Retinal migraine	66	0
Status migrainosus	5	0
Typical aura without headache	15	0
Vestibular migraine	23	0
Mixed cranial nerve disorders		
Bulbar palsy	1	0
Mononeuropathies		
Carpal tunnel syndrome	23	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	2	0
Nerve compression	42	0
Peroneal nerve palsy	10	0
Piriformis syndrome	2	0
Radial nerve palsy	2	0
Sciatic nerve neuropathy	3	0
Ulnar nerve palsy	1	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	48	0
Multiple sclerosis relapse	43	0
Relapsing multiple sclerosis	1	0
Uhthoff's phenomenon	4	0
Muscle tone abnormal		
Hypertonia	2	0
Hypotonia	32	0
Serotonin syndrome	1	0
Stiff leg syndrome	8	0
Myelitis (incl infective)		
Myelitis transverse	64	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	171	0
Narcolepsy	16	0
Nervous system cysts and polyps		
Pineal gland cyst	1	0
Nervous system disorders NEC		
Brain stem syndrome	2	0
Central nervous system lesion	1	0
Cerebral disorder	2	0
Microglial nodules	1	0
Nervous system disorder	40	0
Neurotoxicity	1	0
Psychomotor skills impaired	4	0
Neurologic visual problems NEC		
Hemianopia	7	0
Hemianopia homonymous	1	0
Tunnel vision	16	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	20059	0
Dizziness exertional	88	0
Dizziness postural	1979	1
Drooling	20	0
Exaggerated startle response	3	0
Fontanelle bulging	3	0
Head discomfort	592	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hyporesponsive to stimuli	2	0
Inability to crawl	1	0
Infant irritability	5	0
Intracranial hypotension	2	0
Meningism	2	0
Myoclonus	25	0
Neurological decompensation	4	0
Neurological symptom	89	0
Patient elopement	2	0
Persistent postural-perceptual dizziness	29	0
Pleocytosis	3	0
Presyncope	547	0
Sensory overload	11	0
Slow response to stimuli	5	0
Tongue biting	8	0
Unresponsive to stimuli	85	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	32	0
Muscle spasticity	23	0
Neuromuscular pain	6	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	10	0
Myasthenia gravis crisis	3	0
Olfactory nerve disorders		
Anosmia	263	0
Hyposmia	10	0
Parosmia	348	0
Optic nerve disorders NEC		
Optic neuritis	39	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	25	0
Burning sensation	783	0
Burning sensation mucosal	3	0
Dysaesthesia	7	0
Formication	62	0
Hand-arm vibration syndrome	1	0
Hemianaesthesia	4	0
Hemiparaesthesia	2	0
Hyperaesthesia	244	0
Hypoaesthesia	4769	0
Lhermitte's sign	1	0
Paraesthesia	7970	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	24	0
Hemiparesis	84	0
Hemiplegia	29	0
Monoparesis	80	0
Monoplegia	108	0
Paralysis	256	0
Paraparesis	6	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Paraplegia	2	0
Paresis	5	0
Peripheral nerve palsy	1	0
Postictal paralysis	1	0
Quadriplegia	3	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	152	0
Parkinson's disease	15	0
Parkinsonism	10	0
Reduced facial expression	7	0
Vascular parkinsonism	1	0
Partial complex seizures		
Dreamy state	20	0
Focal dyscognitive seizures	6	0
Temporal lobe epilepsy	4	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Simple partial seizures	5	0
Peripheral neuropathies NEC		
Autoimmune neuropathy	2	0
Axonal neuropathy	1	0
Ischaemic neuropathy	1	0
Neuralgic amyotrophy	6	0
Neuritis	10	0
Neuropathy peripheral	162	0
Peripheral motor neuropathy	1	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	13	0
Polyneuropathy	10	0
Small fibre neuropathy	2	0
Thoracic outlet syndrome	1	0
Seizures and seizure disorders NEC		
Alcoholic seizure	1	0
Atonic seizures	10	0
Change in seizure presentation	7	0
Clonic convulsion	8	0
Convulsive threshold lowered	1	0
Drug withdrawal convulsions	2	0
Epilepsy	256	0
Epileptic aura	2	0
Febrile convulsion	88	0
Migraine-triggered seizure	1	0
Myoclonic epilepsy	4	0
Partial seizures	51	0
Psychogenic seizure	5	0
Seizure	1085	2
Seizure anoxic	3	0
Seizure cluster	6	0
Seizure like phenomena	2	0
Status epilepticus	116	3
Tonic clonic movements	2	0
Tonic convulsion	33	0
Sensory abnormalities NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ageusia	948	0
Allodynia	56	0
Aura	23	0
Central pain syndrome	2	0
Complex regional pain syndrome	10	0
Dysgeusia	1862	0
Electric shock sensation	79	0
Hypogeusia	5	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Neuralgia	1104	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	17	0
Post herpetic neuralgia	10	0
Restless arm syndrome	11	0
Restless legs syndrome	335	0
Sensory disturbance	101	0
Sensory loss	176	0
Taste disorder	465	0
Vibratory sense increased	1	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	2	0
Periodic limb movement disorder	1	0
Sleep deficit	45	0
Speech and language abnormalities		
Dysarthria	329	0
Incoherent	15	0
Language disorder	3	0
Muscle tension dysphonia	1	0
Slow speech	31	0
Speech disorder	75	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	4	0
Myelopathy	3	0
Radicular pain	1	0
Radiculitis brachial	13	0
Radiculopathy	2	0
Spinal cord disorder	3	0
Spinal cord oedema	1	0
Structural brain disorders NEC		
Brain injury	24	2
Cerebral mass effect	6	0
Intracranial mass	3	0
White matter lesion	1	0
Transient cerebrovascular events		
Transient ischaemic attack	378	0
Tremor (excl congenital)		
Action tremor	2	0
Asterixis	1	0
Essential tremor	5	0
Head titubation	15	0
Intention tremor	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Postural tremor	1	0
Resting tremor	5	0
Tremor	9178	3
Trigeminal disorders		
Facial neuralgia	34	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	5	0
Trigeminal neuralgia	77	0
Trigeminal neuritis	2	0
Trigeminal palsy	1	0
Vagus nerve disorders		
Vagus nerve paralysis	1	0
Vocal cord paralysis	1	0
Vertigos NEC		
Vertigo CNS origin	2	0
Nervous system disorders SOC TOTAL	158126	158

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	86	1
<i>Foetal complications NEC</i>		
Foetal disorder	2	0
Foetal hypokinesia	1	0
<i>Foetal position and presentation abnormalities</i>		
Face presentation	2	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Precipitate labour	1	0
Premature labour	3	0
Premature rupture of membranes	1	0
Prolonged labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	1	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	1	0
Ectopic pregnancy	4	0
Hyperemesis gravidarum	2	0
Morning sickness	37	0
Pelvic girdle pain	1	0
Somatic symptom disorder of pregnancy	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Pregnancy	19	0
Uterine contractions during pregnancy	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	5	0
<i>Stillbirth and foetal death</i>		
Stillbirth	3	1
<i>Umbilical cord complications</i>		
Umbilical cord abnormality	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	3	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	3	0
Unintended pregnancy	3	0
Pregnancy conditions SOC TOTAL	189	2

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Device electrical impedance issue	1	0
<i>Device incompatibility issues</i>		
Patient-device incompatibility	1	0
<i>Device issues NEC</i>		
Device issue	3	0
Device leakage	2	0
<i>Device malfunction events NEC</i>		
Oversensing	25	0
Stent malfunction	1	0
Thrombosis in device	37	0
Undersensing	3	0
<i>Device physical property and chemical issues</i>		
Needle issue	9	0
Syringe issue	1	0
<i>Manufacturing facilities and equipment issues</i>		
Manufacturing equipment issue	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	1	0
<i>Product distribution and storage issues</i>		
Product temperature excursion issue	3	0
<i>Product label issues</i>		
Product barcode issue	1	0
Product label issue	2	0
<i>Product packaging issues</i>		
Product container issue	1	0
<i>Product physical issues</i>		
Product colour issue	1	0
Product leakage	1	0
Product odour abnormal	1	0
Product physical issue	1	0
Product taste abnormal	7	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	110	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	17	0
Breath holding	4	0
Sexually inappropriate behaviour	1	0
Staring	9	0
<i>Abnormal food elimination</i>		
Self-induced vomiting	1	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	5	0
Adjustment disorder with mixed anxiety and depressed mood	1	0
<i>Affect alterations NEC</i>		
Affect lability	9	0
Constricted affect	5	0
Flat affect	10	0
Inappropriate affect	16	0
<i>Amnesic symptoms</i>		
Paramnesia	4	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
Generalised anxiety disorder	2	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	176	0
Anxiety	924	0
Immunisation anxiety related reaction	1	0
Nervousness	547	0
Procedural anxiety	1	0
Stress	101	0
Tension	59	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	15	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	11	0
Antisocial behaviour	1	0
Asocial behaviour	1	0
Aversion	1	0
Disinhibition	1	0
Impatience	2	0
Indifference	8	0
Paranoia	37	0
Personality change	6	0
Social avoidant behaviour	4	0
Soliloquy	3	0
Violence-related symptom	3	0
<i>Bipolar disorders</i>		
Bipolar I disorder	6	0
Bipolar disorder	3	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Change in sustained attention	1	0
Daydreaming	13	0
Distractibility	1	0
Mental fatigue	414	0
<i>Communications disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Communication disorder	4	0
Mutism	4	0
Speech sound disorder	2	0
Confusion and disorientation		
Confusional state	1815	1
Disorientation	648	0
Decreased physical activity levels		
Catatonia	2	0
Deliria		
Delirium	444	0
Delirium febrile	3	0
Delusional disorders		
Alice in wonderland syndrome	3	0
Delusional symptoms		
Delusion	42	0
Delusion of parasitosis	1	0
Mixed delusion	1	0
Thought withdrawal	1	0
Depressive disorders		
Agitated depression	3	0
Depression	503	0
Depression suicidal	13	0
Major depression	21	0
Mixed anxiety and depressive disorder	2	0
Dissociative states		
Depersonalisation/derealisation disorder	15	0
Dissociation	64	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	38	0
Insomnia	2766	0
Middle insomnia	70	0
Terminal insomnia	11	0
Dyssomnias		
Dyssomnia	4	0
Poor quality sleep	601	0
Eating disorders NEC		
Eating disorder	9	0
Pica	1	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	69	0
Dysphoria	2	0
Emotional disorder	86	0
Emotional distress	64	0
Emotional poverty	2	0
Euphoric mood	60	0
Frustration tolerance decreased	6	0
Irritability	274	0
Mood altered	65	0
Factitious disorders		
Factitious disorder	4	0

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Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Acrophobia	1	0
Agoraphobia	3	0
Fear	37	0
Fear of death	13	0
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	2	0
Fear of open spaces	1	0
Performance fear	1	0
Phobia	2	0
Phonophobia	3	0
<i>Fluctuating mood symptoms</i>		
Mood swings	75	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	865	0
Hallucination, auditory	42	0
Hallucination, olfactory	9	0
Hallucination, tactile	1	0
Hallucination, visual	52	0
Hallucinations, mixed	8	0
Somatic hallucination	1	0
<i>Impulse control disorders</i>		
Impulse-control disorder	2	0
Impulsive behaviour	1	0
Intermittent explosive disorder	1	0
<i>Increased physical activity levels</i>		
Restlessness	446	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
Emotional disorder of childhood	1	0
<i>Mental disorders NEC</i>		
Mental disorder	15	0
Mental status changes	3	0
<i>Mental disorders due to a general medical condition NEC</i>		
Mental disorder due to a general medical condition	1	0
Neuropsychiatric symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	4	0
Decreased interest	12	0
Depressed mood	528	0
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	17	0
Negative thoughts	8	0
Sense of a foreshortened future	1	0
Tearfulness	96	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	30	0
<i>Mood disorders NEC</i>		
Affective disorder	3	0
Apathy	51	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Laziness	1	0
Listless	118	0
Mood disorder due to a general medical condition	1	0
Substance-induced mood disorder	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	4	0
Sleep attacks	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Body dysmorphic disorder	2	0
Compulsive shopping	2	0
Dermatillomania	1	0
Obsessive thoughts	3	0
Obsessive-compulsive disorder	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	3	0
Female orgasmic disorder	1	0
Orgasm abnormal	1	0
Orgasmic sensation decreased	4	0
Premature ejaculation	2	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	260	0
Panic disorder	3	0
Panic reaction	31	0
<i>Paraphilias and paraphilic disorders</i>		
Fetishism	2	0
<i>Parasomnias</i>		
Abnormal dreams	341	0
Abnormal sleep-related event	1	0
Confusional arousal	2	0
Exploding head syndrome	6	0
Nightmare	417	0
Parasomnia	1	0
Rapid eye movements sleep abnormal	4	0
Sleep inertia	1	0
Sleep talking	16	0
Sleep terror	56	0
Sleep-related eating disorder	2	0
Somnambulism	9	0
<i>Perception disturbances NEC</i>		
Autoscopy	23	0
Deja vu	4	0
Delusional perception	2	0
Derealisation	13	0
Flashback	2	0
Illusion	11	0
Pseudohallucination	1	0
Time perception altered	5	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	3	0
<i>Psychiatric elimination disorders</i>		
Enuresis	45	0
<i>Psychiatric symptoms NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Helplessness	2	0
Hypervigilance	13	0
Psychiatric symptom	7	0
Psychological trauma	4	0
Psychotic disorder NEC		
Acute psychosis	4	0
Psychotic behaviour	2	0
Psychotic disorder	34	0
Psychotic symptom	1	0
Rebound psychosis	1	0
Schizoaffective and schizophreniform disorders		
Schizoaffective disorder	1	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	3	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	14	0
Libido increased	5	0
Loss of libido	35	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	345	0
Sleep disorder due to general medical condition, insomnia type	2	0
Somatic symptom disorders		
Conversion disorder	17	0
Habit cough	32	0
Illness anxiety disorder	1	0
Psychogenic tremor	2	0
Somatic symptom disorder	1	0
Speech and language usage disturbances		
Disorganised speech	16	0
Logorrhoea	3	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
Speech articulation and rhythm disturbances		
Dysphemia	26	0
Lack of spontaneous speech	3	0
Stereotypies and automatisms		
Bruxism	31	0
Head banging	39	0
Waxy flexibility	2	0
Stress disorders		
Acute stress disorder	2	0
Burnout syndrome	11	0
Hyperarousal	3	0
Post-traumatic stress disorder	12	0
Substance related and addictive disorders		
Alcohol abuse	2	0
Alcohol use disorder	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Alcoholic hangover	1	0
Alcoholism	3	0
Dependence	2	0
Drug abuse	1	0
Drug dependence	1	0
Substance abuse	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	2	2
Intentional self-injury	8	0
Self-injurious ideation	2	0
Suicidal behaviour	3	0
Suicidal ideation	94	0
Suicide attempt	17	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	80	0
Confabulation	1	0
Illogical thinking	1	0
Impaired reasoning	3	0
Intrusive thoughts	5	0
Morbid thoughts	4	0
Tachyphrenia	23	0
Thinking abnormal	23	0
Thought blocking	4	0
<i>Tic disorders</i>		
Secondary tic	1	0
Tic	9	0
Psychiatric disorders SOC TOTAL	14883	3

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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	51	0
Bladder spasm	1	0
Dysuria	70	0
Incontinence	68	0
Micturition disorder	3	0
Micturition frequency decreased	1	0
Micturition urgency	95	0
Mixed incontinence	1	0
Pollakiuria	256	0
Urethral pain	5	0
Urge incontinence	2	0
Urinary hesitation	5	0
Urinary incontinence	105	0
Urinary retention	69	0
Urine flow decreased	12	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	15	0
Urinary bladder haemorrhage	9	1
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	7	0
Cystitis noninfective	3	0
Lupus cystitis	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	6	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	2	0
Glomerulonephritis membranoproliferative	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	3	0
Henoch-Schonlein purpura nephritis	1	0
IgA nephropathy	3	0
Nephrotic syndrome	13	0
<i>Myoneurogenic bladder disorders</i>		
Automatic bladder	1	0
Bladder dysfunction	3	0
Hypertonic bladder	13	0
Loss of bladder sensation	11	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	5	0
Tubulointerstitial nephritis	4	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	3	0
<i>Renal disorders NEC</i>		
Oedematous kidney	1	0
Renal disorder	8	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal haemorrhage	2	0
Renal failure and impairment		
Acute kidney injury	46	1
Anuria	5	0
Chronic kidney disease	8	0
End stage renal disease	1	0
Oliguria	10	0
Renal failure	25	3
Renal impairment	13	0
Renal injury	4	0
Renal hypertension and related conditions		
Hypertensive nephropathy	1	0
Renal lithiasis		
Nephrolithiasis	14	0
Renal obstructive disorders		
Hydronephrosis	1	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Renal atrophy	2	0
Renal vascular and ischaemic conditions		
Renal artery occlusion	1	0
Renal embolism	1	0
Renal infarct	12	1
Renal tubular injury	1	0
Renal vascular thrombosis	1	0
Renal vein embolism	1	0
Renal vein occlusion	2	0
Renal vein thrombosis	8	0
Structural and obstructive urethral disorders (excl congenital)		
Urethral spasm	1	0
Ureteric disorders NEC		
Ureteral disorder	2	0
Urinary abnormalities		
Chromaturia	90	0
Glycosuria	1	0
Haematuria	54	0
Microalbuminuria	1	0
Proteinuria	7	0
Urine abnormality	17	0
Urine odour abnormal	19	0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	41	0
Nocturia	18	0
Polyuria	30	0
Renal colic	2	0
Renal pain	855	0
Urinary tract discomfort	1	0
Urinary tract pain	12	0
Renal & urinary disorders SOC TOTAL	2191	6

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	7	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	5	0
Breast mass	42	0
Gynaecomastia	7	0
Mammary duct ectasia	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	2	0
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	8	0
Breast discolouration	1	0
Breast discomfort	8	0
Breast engorgement	5	0
Breast haemorrhage	1	0
Breast induration	1	0
Breast oedema	1	0
Breast pain	354	0
Breast swelling	48	0
Breast tenderness	46	0
Nipple exudate bloody	1	0
Nipple pain	31	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Cervix haemorrhage uterine	1	0
Ectropion of cervix	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation disorder	3	0
Ejaculation failure	4	0
Erectile dysfunction	60	0
Erection increased	4	0
Organic erectile dysfunction	18	0
Painful erection	1	0
Priapism	3	0
Retrograde ejaculation	2	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
Lactation disorder	2	0
Lactation puerperal increased	3	0
Suppressed lactation	23	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal disorder	2	0
Menopausal symptoms	28	0
Menopause delayed	3	0
Premature menopause	10	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	181	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	4	0
Abnormal withdrawal bleeding	4	0
Dysmenorrhoea	363	0
Intermenstrual bleeding	275	0
Menstrual discomfort	4	0
Menstrual disorder	523	0
Menstruation irregular	685	0
Premenstrual headache	2	0
Premenstrual pain	25	0
Premenstrual syndrome	15	0
Retrograde menstruation	2	0
Withdrawal bleed	9	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	190	0
Hypomenorrhoea	160	0
Menstruation delayed	885	0
Oligomenorrhoea	37	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1478	0
Menometrorrhagia	8	0
Polymenorrhoea	216	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	11	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	16	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Fallopian tube spasm	1	0
Ovarian enlargement	1	0
Ovarian haemorrhage	3	0
Ovarian necrosis	1	0
Ovarian oedema	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	18	0
Premature ovulation	2	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	26	0
Pelvic haematoma	1	0
Pelvic haemorrhage	11	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile blister	6	0
Penile burning sensation	1	0
Penile curvature	2	0
Penile discharge	2	0
Penile exfoliation	1	0
Penile haemorrhage	4	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Penile oedema	3	0
Penile pain	1	0
Penile size reduced	1	0
Penis disorder	7	0
Peyronie's disease	4	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	4	0
Prostatic neoplasms and hypertrophy		
Benign prostatic hyperplasia	2	0
Prostatic signs, symptoms and disorders NEC		
Prostatism	1	0
Prostatomegaly	3	0
Reproductive tract disorders NEC (excl neoplasms)		
Female genital tract fistula	1	0
Genital blister	3	0
Genital haemorrhage	15	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	2	0
Genital lesion	1	0
Genital paraesthesia	2	0
Genital ulceration	12	0
Perineal disorder	2	0
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	2	0
Reproductive tract neoplasms NEC		
Genital cyst	1	0
Reproductive tract signs and symptoms NEC		
Genital burning sensation	7	0
Genital discomfort	3	0
Genital erythema	1	0
Genital pain	3	0
Genital rash	2	0
Pelvic discomfort	2	0
Pelvic pain	119	0
Perineal pain	1	0
Pruritus genital	6	0
Scrotal disorders NEC		
Scrotal dermatitis	1	0
Scrotal oedema	1	0
Scrotal pain	11	0
Scrotal swelling	5	0
Varicocele	1	0
Sexual function and fertility disorders NEC		
Dyspareunia	3	0
Female sexual dysfunction	1	0
Infertility	1	0
Infertility female	1	0
Infertility male	2	0
Male sexual dysfunction	1	0
Sexual dysfunction	7	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haemospermia	7	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
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	90	0
Testicular retraction	2	0
Testicular swelling	16	0
Testis discomfort	3	0
<i>Testicular and epididymal neoplasms</i>		
Epididymal cyst	1	0
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	5	0
Endometriosis	37	0
Metrorrhoea	1	0
Uterine enlargement	1	0
Uterine haemorrhage	37	0
Uterine pain	6	0
<i>Uterine neoplasms</i>		
Uterine cyst	1	0
Uterine polyp	3	0
<i>Uterine tone disorders</i>		
Uterine spasm	12	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	11	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal disorder	1	0
Vaginal haemorrhage	609	0
Vaginal ulceration	6	0
Vulval disorder	2	0
Vulval haemorrhage	18	0
Vulval ulceration	4	0
Vulvovaginal ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Enlarged clitoris	1	0
Labia enlarged	2	0
Vaginal discharge	44	0
Vaginal lesion	4	0
Vaginal odour	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	7	0
Vulvovaginal discomfort	7	0
Vulvovaginal dryness	7	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	25	0
Vulvovaginal pruritus	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	7186	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	11	0
Apnoeic attack	1	0
Dyspnoea	6071	5
Dyspnoea at rest	15	0
Dyspnoea exertional	38	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	86	0
Hypopnoea	200	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	7	0
Orthopnoea	3	0
Respiration abnormal	89	0
Respiratory arrest	19	0
Respiratory distress	10	0
Respiratory fatigue	6	0
Sleep apnoea syndrome	26	0
Tachypnoea	35	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	504	0
Asthma exercise induced	1	0
Asthma late onset	2	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	2	0
Asthmatic crisis	5	0
Bronchitis chronic	1	0
Bronchospasm	16	0
Chronic obstructive pulmonary disease	35	3
Cough variant asthma	6	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	528	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Hypercapnia	1	0
Hypoxia	61	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	3451	0
Haemoptysis	108	0
Productive cough	165	0
Sputum discoloured	11	0
Sputum increased	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	2	0
Vocal cord disorder	1	0
Vocal cord thickening	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Laryngeal oedema	2	0
Laryngospasm	2	0
Stridor	20	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	2	0
Eosinophilic pneumonia	1	0
Pneumonia aspiration	22	5
Pneumonitis	23	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	40	0
Lower respiratory tract congestion	4	0
Lung opacity	6	0
Pleuritic pain	34	0
Pulmonary haemorrhage	6	1
Pulmonary pain	188	0
Rales	2	0
<i>Mediastinal disorders</i>		
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	423	0
Nasal inflammation	8	0
Rhinitis allergic	22	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1911	0
Intranasal hyposaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	5	0
Nasal dryness	56	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	12	0
Nasal polyps	1	0
Nasal pruritus	9	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	3	0
<i>Neonatal hypoxic conditions</i>		
Cyanosis neonatal	1	0
Gasping syndrome	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	2	0
Sinonasal obstruction	10	0
Sinus congestion	76	0
Sinus disorder	13	0
Sinus polyp	1	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	5	0
Emphysema	2	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Idiopathic pulmonary fibrosis	1	0
Interstitial lung disease	14	0
Lung consolidation	5	0
Lung cyst	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	2	0
Pulmonary fibrosis	5	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Oropharyngeal swelling	2	0
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	36	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	11	0
Pharyngeal paraesthesia	30	0
Pharyngeal swelling	246	0
Pharyngeal ulceration	14	0
Tonsillar disorder	1	0
Tonsillar erythema	6	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	60	0
Tonsillar inflammation	4	0
Tonsillar ulcer	2	0
Tonsillolith	1	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pleural infections and inflammations</i>		
Lupus pleurisy	2	0
Pleurisy	42	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	28	0
Pneumothorax	7	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	15	0
Pulmonary oedema	25	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	1236	83
Pulmonary infarction	12	1
Pulmonary thrombosis	21	2
Pulmonary venous thrombosis	2	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
Respiratory failure	20	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	9	0

Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Diaphragmalgia	13	0
Nasal flaring	1	0
Painful respiration	7	0
Pleural rub	1	0
Respiratory symptom	15	0
Suffocation feeling	5	0
Respiratory tract disorders NEC		
Aspiration	9	2
Chronic respiratory disease	2	1
Lung disorder	6	0
Pulmonary mass	3	0
Respiratory disorder	7	0
Respiratory tract congestion	7	0
Respiratory tract haemorrhage	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	1	0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	1	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal fistula	1	0
Tracheal pain	4	0
Upper respiratory tract signs and symptoms		
Aphonia	84	0
Catarrh	54	0
Choking	17	0
Choking sensation	8	0
Dry throat	240	0
Dysphonia	125	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	18	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	102	0
Nasal obstruction	1	0
Oropharyngeal blistering	24	0
Oropharyngeal discomfort	33	0
Oropharyngeal pain	3824	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	61	0
Rhinalgia	32	0
Rhinorrhoea	1523	0
Sinus pain	544	0
Sneezing	432	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	184	0
Throat lesion	1	0
Throat tightness	183	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	24	0
Yawning	61	0
Vascular pulmonary disorders NEC		

Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	24089	110

Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	84	0
Acne cystic	4	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	238	0
Alopecia areata	20	0
Alopecia scarring	1	0
Alopecia totalis	1	0
Alopecia universalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	3	0
Madarosis	2	0
<i>Angioedemas</i>		
Angioedema	304	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1584	0
Hyperhidrosis	8545	0
Hypohidrosis	3	0
Miliaria	194	0
Night sweats	1734	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	444	0
Blister rupture	7	0
Blood blister	84	0
Dermatitis bullous	12	0
Dermatitis herpetiformis	2	0
Erythema multiforme	33	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	20	0
Pemphigus	1	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	4	0
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	1	0
Cutaneous lupus erythematosus	1	0
Dermatomyositis	3	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	2	0
Dry skin	385	0
Macule	10	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	861	0
Papule	95	0
Peau d'orange	3	0

Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Scab	24	0
Scar pain	11	0
Sensitive skin	547	0
Skin burning sensation	512	0
Skin discolouration	151	0
Skin discomfort	5	0
Skin disorder	22	0
Skin fissures	11	0
Skin fragility	1	0
Skin indentation	14	0
Skin induration	14	0
Skin laxity	1	0
Skin lesion	39	0
Skin necrosis	5	0
Skin odour abnormal	46	0
Skin plaque	3	0
Skin reaction	231	0
Skin sensitisation	83	0
Skin swelling	82	0
Skin texture abnormal	1	0
Skin tightness	32	0
Skin warm	537	0
Skin weeping	5	0
Sticky skin	7	0
Target skin lesion	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	27	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	162	0
Dermatitis allergic	269	0
Dermatitis atopic	19	0
Dermatitis contact	19	0
Dermatitis diaper	2	0
Dyshidrotic eczema	8	0
Eczema	237	0
Eczema asteatotic	13	0
Eczema nummular	3	0
Eczema weeping	2	0
Hand dermatitis	6	0
Intertrigo	2	0
Perioral dermatitis	4	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	7	0
Skin irritation	120	0
Stasis dermatitis	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	31	0
Drug reaction with eosinophilia and systemic symptoms	12	0
Fixed eruption	4	0
Palmar-plantar erythrodysesthesia syndrome	2	0
<i>Erythemas</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Erythema	3090	0
Erythema ab igne	1	0
Palmar erythema	5	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	14	0
Skin exfoliation	125	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	4	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
<i>Hyperpigmentation disorders</i>		
Chloasma	1	0
Melanoderma	2	0
Skin hyperpigmentation	6	0
Solar lentigo	5	0
<i>Hypertrichoses</i>		
Hypertrichosis	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	7	0
Skin hypopigmentation	2	0
Vitiligo	14	0
<i>Lipodystrophies</i>		
Lipoatrophy	2	0
Lipohypertrophy	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Ingrowing nail	1	0
Nail bed disorder	2	0
Nail bed tenderness	1	0
Nail discolouration	9	0
Nail disorder	1	0
Nail growth abnormal	1	0
Nail hypertrophy	1	0
Nail necrosis	1	0
Nail pigmentation	1	0
Nail pitting	1	0
Nail ridging	6	0
Onychalgia	4	0
Onychoclasia	9	0
Onycholysis	2	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<i>Panniculitides</i>		
Erythema nodosum	26	0
Panniculitis	4	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	20	0
Lichen sclerosus	3	0
Parapsoriasis	1	0
Pityriasis rosea	49	0
Pityriasis rubra pilaris	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Photosensitivity and photodermatosis conditions</i>		
Photodermatosis	2	0
Photosensitivity reaction	140	0
Polymorphic light eruption	3	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	11	0
<i>Pilar disorders NEC</i>		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	6	0
Hair texture abnormal	7	0
Piloerection	88	0
Pseudofolliculitis	1	0
Trichodynia	6	0
Trichorrhexis	2	0
<i>Pruritus NEC</i>		
Itching scar	4	0
Pruritus	7206	0
Pruritus allergic	1	0
Senile pruritus	1	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	23	0
Psoriasis	159	0
Pustular psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	6	0
Henoch-Schonlein purpura	13	0
Petechiae	277	0
Purpura	107	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	7752	1
Rash erythematous	2035	0
Rash macular	663	0
Rash maculo-papular	58	0
Rash morbilliform	42	0
Rash papular	489	0
Rash pruritic	1688	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	72	0
Systemic lupus erythematosus rash	8	0
<i>Rosaceas</i>		
Erythematotelangiectatic rosacea	1	0
Rosacea	34	0
<i>Scaly conditions</i>		
Pityriasis	8	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	8	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin and subcutaneous conditions NEC</i>		
Adiposis dolorosa	1	0
Cutaneous symptom	8	0
Eosinophilic cellulitis	1	0
Skin mass	32	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Diabetic foot	2	0
Diabetic ulcer	1	0
Pyoderma gangrenosum	2	0
Skin erosion	41	0
Skin ulcer	25	0
<i>Skin cysts and polyps</i>		
Dermal cyst	17	0
<i>Skin dystrophies</i>		
Skin wrinkling	3	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	16	0
Mucocutaneous haemorrhage	3	0
Skin haemorrhage	32	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	8	0
Skin striae	8	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	3	0
Needle track marks	3	0
<i>Skin preneoplastic conditions NEC</i>		
Actinic keratosis	2	0
Leukoplakia	1	0
<i>Skin vascular conditions NEC</i>		
Angiodermatitis	1	0
Skin oedema	3	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	9	0
Hypersensitivity vasculitis	3	0
Vasculitic rash	24	1
<i>Skin vasomotor conditions</i>		
Livedo reticularis	51	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	4	0
Telangiectasia	3	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	3	0
Cold urticaria	3	0
Idiopathic urticaria	8	0
Mechanical urticaria	2	0
Solar urticaria	1	0
Urticaria	2152	0
Urticaria chronic	24	0
Urticaria contact	2	0
Urticaria papular	2	0
Urticaria pigmentosa	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Urticaria thermal	5	0
Urticarial vasculitis	6	0
Skin disorders SOC TOTAL	44966	2

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Report Run Date: 14-Jun-2021
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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	2	0
Menopause	25	0
Postmenopause	6	0
<i>Bereavement issues</i>		
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	75	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	39	0
Immobilisation prolonged	4	0
Impaired driving ability	4	0
Impaired work ability	17	0
Loss of personal independence in daily activities	5	0
Paralytic disability	1	0
Sight disability	16	0
Sitting disability	2	0
Walking disability	2	0
<i>Educational issues</i>		
Illiteracy	2	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	5	0
Stress at work	1	0
<i>Family and partner issues</i>		
Homosexual parent	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Food contamination	1	0
Water pollution	3	0
<i>Pregnancy related circumstances</i>		
Breast feeding	7	0
<i>Sexuality issues</i>		
Anal sex	1	0
Homosexuality	1	0
<i>Social issues NEC</i>		
Blood donor	2	0
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
Hair dye user	1	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Impaired quality of life	1	0
Refusal of vaccination	1	0
Tanning	1	0
Tattoo	1	0
Tobacco use		
Non-tobacco user	4	0
Tobacco user	2	0
Social circumstances SOC TOTAL	255	1

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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	27	0
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	2	0
Haematological therapeutic procedures NEC		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	1	0
Head, neck and oral cavity therapeutic procedures NEC		
Neck lift	1	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	3	0
Hormone therapy	2	0
Immunisations		
COVID-19 immunisation	186	1
Immunisation	84	0
Tuberculosis immunisation	1	0
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Hip surgery	1	0
Joint injection	2	0
Joint stabilisation	1	0
Knee operation	1	0
Large intestine therapeutic procedures		
Appendectomy	5	0
Limb therapeutic procedures		
Foot amputation	1	0
Leg amputation	3	0
Limb immobilisation	24	0
Limb operation	9	0
Limb reattachment surgery	1	0
Toe amputation	4	0
Mastectomies		
Breast conserving surgery	2	0
Muscle therapeutic procedures		
Muscle relaxant therapy	2	0
Nasal therapeutic procedures		
Nasal irrigation	1	0
Nervous system therapeutic procedures NEC		
Central nervous system stimulation	3	0
Orbit and globe therapeutic procedures		
Eye muscle operation	1	0
Patient positioning		
Prone position	1	0
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

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	1	0
<i>Skin lesion excisions</i>		
Tattoo excision	1	0
<i>Small intestine therapeutic procedures</i>		
Ileostomy	2	0
<i>Spine and spinal cord therapeutic procedures</i>		
Spinal operation	1	0
<i>Testicular and scrotal therapeutic procedures</i>		
Testes exploration	1	0
<i>Therapeutic procedures NEC</i>		
Anaphylaxis treatment	3	0
Antiallergic therapy	1	0
Bed rest	20	0
Catheter management	4	0
Catheter placement	1	0
Fatigue management	1	0
Heat therapy	2	0
Hospitalisation	20	0
Immobilisation bandage	1	0
Injection	35	0
Interchange of vaccine products	3	0
Localised alternating hot and cold therapy	5	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	1	0
Physical fitness training	4	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
Therapeutic hypothermia	2	0
Therapy change	1	0
Transgender operation	1	0
Tumour excision	1	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	2	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	579	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	10	0
Hypertensive emergency	1	0
Hypertensive urgency	3	0
Malignant hypertension	4	0
Tyramine reaction	1	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	9	2
Aneurysm ruptured	1	0
Artery dissection	1	0
Venous aneurysm	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	5	0
Aortic dissection	2	1
Aortic intramural haematoma	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	20	1
Aortic thrombosis	11	2
<i>Aortic infections and inflammations</i>		
Aortitis	2	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	50	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	20	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	6	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	98	1
Distributive shock	2	0
Hypoperfusion	3	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	3	0
Shock	49	1
Shock symptom	5	0
<i>Haemorrhages NEC</i>		
Bloody discharge	11	0
Haematoma	86	0
Haemorrhage	725	2
Internal haemorrhage	24	0
Venous haemorrhage	8	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
Lymphorrhoea	1	0
<i>Lymphoedemas</i>		
Lymphoedema	55	0

Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 09-Jun-2021 19:00:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	23	1
Atheroembolism	1	0
Embolism	249	3
Embolism arterial	2	0
Embolism venous	12	1
Microembolism	3	0
Paradoxical embolism	1	0
Thrombophlebitis migrans	1	0
Thrombosis	1243	23
Venous thrombosis	29	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	11	0
Arterial spasm	2	0
Arterial stenosis	1	0
Arteriosclerosis	4	0
Infarction	9	0
Ischaemia	11	0
Peripheral venous disease	5	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	9	0
Collateral circulation	1	0
Haemodynamic instability	3	0
Hyperaemia	2	0
Neovascularisation	1	0
Superficial vein prominence	4	0
Vascular pain	102	0
Vascular rupture	1	0
Vascular wall discolouration	1	0
Vasodilatation	90	0
Vein collapse	1	0
Vein discolouration	5	0
Vein disorder	17	0
Vein rupture	13	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	34	0
Deep vein thrombosis	928	7
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	20	0
Pelvic venous thrombosis	15	1
Peripheral artery thrombosis	17	0
Peripheral embolism	9	0
Peripheral vein thrombus extension	1	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	2	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Thrombophlebitis	102	0
Thrombophlebitis superficial	51	0
Venous thrombosis limb	2	0
Peripheral vascular disorders NEC		
Cyanosis	97	0
Erythromelalgia	6	0
Flushing	657	0
Hot flush	1915	0
Peripheral vascular disorder	4	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Dry gangrene	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	4	0
Ischaemic limb pain	4	0
Jugular vein occlusion	1	0
Peripheral arterial occlusive disease	3	0
Peripheral artery occlusion	7	0
Peripheral coldness	1185	0
Peripheral ischaemia	30	2
Poor peripheral circulation	47	0
Raynaud's phenomenon	124	0
Phlebitis NEC		
Phlebitis	49	0
Phlebitis superficial	9	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	384	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	1	0
Spider vein	12	0
Varicophlebitis	6	0
Varicose ulceration	1	0
Varicose vein	111	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	5	0
Hypertension	761	0
Labile hypertension	1	0
Systolic hypertension	2	0
Venous hypertension	3	0
White coat hypertension	11	0
Vascular hypotensive disorders		
Capillary leak syndrome	8	0
Hypotension	468	0
Orthostatic hypotension	43	0
Vascular malformations and acquired anomalies		
Arteriovenous fistula	1	0
Vasculitides NEC		
Behcet's syndrome	2	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	113	4
<i>Vena caval embolism and thrombosis</i>		
Vena cava thrombosis	3	1
Vascular disorders SOC TOTAL	10392	55
TOTAL REACTIONS FOR DRUG	732790	885
TOTAL REPORTS	200860	
TOTAL FATAL OUTCOME REPORTS		885