

COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Data Lock Date: 02-Jun-2021 18:30:03

All UK spontaneous reports received between 04/01/21 and 02/06/21 for COVID-19 vaccine Oxford University/AstraZeneca.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	7	0
Iron deficiency anaemia	8	0
Pernicious anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	79	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	89	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	44	0
Disseminated intravascular coagulation	15	1
Hypercoagulation	18	1
<i>Eosinophilic disorders</i>		
Eosinophilia	16	0
Hypereosinophilic syndrome	1	0
<i>Haematological cysts and polyps</i>		
Splenic cyst	1	0
<i>Haematological disorders</i>		
Blood disorder	7	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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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Lymph node fibrosis	1	0
Lymph node pain	497	0
Lymphadenitis	26	0
Lymphadenopathy	4271	0
Lymphatic disorder	1	0
Pseudolymphoma	3	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Myelosuppression	3	0
Pancytopenia	16	0
<i>Neutropenias</i>		
Agranulocytosis	4	0
Autoimmune neutropenia	1	0
Febrile neutropenia	1	0
Neutropenia	71	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	3	0
Platelet disorder	6	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	1	0
Stress polycythaemia	3	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	4	0
<i>Red blood cell abnormal findings NEC</i>		
Anisocytosis	1	0
Macrocytosis	2	0
Poikilocytosis	1	0
Polychromasia	3	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	11	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	9	0
Splenomegaly	4	0
<i>Thrombocytopenias</i>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	11	0
Immune thrombocytopenia	183	1
Thrombocytopenia	731	6
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	2	0
<i>Thrombocytoses</i>		
Thrombocytosis	8	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	6311	9

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Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	15	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	2	0
Cardiac disorder	50	0
Cardiac dysfunction	1	0
Cardiac ventricular thrombosis	8	2
Cardiovascular disorder	7	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	11	0
Cardiovascular symptom	1	0
Palpitations	4367	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	8	1
Congestive cardiomyopathy	8	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	2	1
Coronary artery disease	6	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	6
Cardiac failure acute	5	0
Cardiac failure congestive	2	1
Cardiogenic shock	7	2
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	7	0

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Cardiac disorders Cardiac disorders cont'd		
Acute myocardial infarction	50	7
Angina pectoris	164	0
Angina unstable	13	0
Arteriospasm coronary	5	0
Microvascular coronary artery disease	2	0
Myocardial infarction	280	40
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	11	0
Diastolic dysfunction	1	0
Left atrial dilatation	1	0
Left ventricular dilatation	2	0
Left ventricular dysfunction	12	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	31	1
Noninfectious pericarditis		
Pericarditis	55	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	17	0
Pericardial haemorrhage	4	2
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	103	1
Bradycardia	66	0
Cardiac fibrillation	3	0
Cardiac flutter	173	0
Extrasystoles	108	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	11	0
Tachyarrhythmia	10	0
Tachycardia	1137	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	3	1
Supraventricular arrhythmias		
Arrhythmia supraventricular	13	0
Atrial fibrillation	250	0
Atrial flutter	26	0

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Cardiac disorders Cardiac disorders cont'd		
Atrial tachycardia	3	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	2	0
Sinus node dysfunction	1	0
Sinus tachycardia	61	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	29	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	5	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	137	31
Cardio-respiratory arrest	2	1
Pulseless electrical activity	4	1
Ventricular arrhythmia	1	0
Ventricular extrasystoles	8	0
Ventricular fibrillation	5	0
Ventricular tachycardia	12	0
Cardiac disorders SOC TOTAL	7494	118

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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	3	0
Congenital hydrocephalus	1	0
<i>Coagulation disorders congenital</i>		
Protein C deficiency	3	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	1	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>Lysosomal storage disorders</i>		
Mucopolysaccharidosis	1	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
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>		
Colour blindness	1	0
<i>Pancreatic disorders congenital</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Hereditary pancreatitis	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	11	0
Pulmonary and bronchial disorders congenital		
Cystic fibrosis	2	0
Sex chromosomal abnormalities		
Klinefelter's syndrome	1	0
Tongue disorders congenital		
Ankyloglossia congenital	1	0
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	65	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	23	0
Ear discomfort	88	0
Ear disorder	10	0
Ear haemorrhage	11	0
Ear pain	1773	0
Ear pruritus	5	0
Ear swelling	62	0
Otorrhoea	6	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	3	0
Eustachian tube dysfunction	1	0
Eustachian tube obstruction	5	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	26	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	5	0
<i>Hearing losses</i>		
Deafness	266	0
Deafness bilateral	12	0
Deafness neurosensory	17	0
Deafness transitory	3	0
Deafness unilateral	39	0
Hypoacusis	161	0
Neurosensory hypoacusis	1	0
Sudden hearing loss	47	0
<i>Hyperacusia</i>		
Hyperacusis	110	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	97	0
Phobic postural vertigo	2	0
Tinnitus	3050	0
Vertigo	1657	0
Vertigo labyrinthine	10	0
Vertigo positional	100	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
Ear disorders SOC TOTAL	7656	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	6	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	5	0
Inappropriate antidiuretic hormone secretion	1	0
<i>Thyroid disorders NEC</i>		
Goitre	13	0
Thyroid disorder	13	0
Thyroid mass	3	0
Thyroid pain	11	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	4	0
Hyperthyroidism	27	0
Thyrotoxic crisis	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	38	0

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Reaction Name	Total	Fatal
Endocrine disorders Endocrine disorders cont'd		
Endocrine disorders SOC TOTAL	239	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	7	0
<i>Cataract conditions</i>		
Cataract	13	0
Cataract cortical	2	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	134	0
Vitreous opacities	1	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	15	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	106	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	104	0
Excessive eye blinking	7	0
Eyelid ptosis	40	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	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	18	0
Iritis	10	0
Uveitis	29	0
<i>Lacrimation disorders</i>		
Dry eye	252	0
Lacrimation increased	214	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	17	0
Chalazion	2	0
Eczema eyelids	2	0
Erythema of eyelid	5	0
Eyelid cyst	11	0

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Eye disorders Eye disorders cont'd		
Eyelid irritation	3	0
Eyelid margin crusting	1	0
Eyelid oedema	11	0
Eyelid rash	10	0
Swelling of eyelid	106	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	84	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	6	0
Eye disorder	21	0
Eye oedema	14	0
Eye pain	2995	0
Eye swelling	514	0
Eye symptom	9	0
Eye ulcer	9	0
Eyelid disorder	8	0
Eyelid pain	16	0
Eyelids pruritus	7	0
Ocular discomfort	60	0
Periorbital discomfort	1	0
Periorbital oedema	15	0
Periorbital pain	3	0
Periorbital swelling	85	0
Retinal disorder	1	0
Ocular infections, inflammations and associated manifestations		
Autoimmune eye disorder	1	0
Eye allergy	24	0
Eye discharge	21	0
Eye inflammation	26	0
Eye irritation	182	0
Eye pruritus	254	0
Limbal swelling	6	0
Ocular hyperaemia	370	0
Ocular rosacea	1	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	10	0
Eye movement disorder	39	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	23	0
Asthenopia	308	0
Eye paraesthesia	4	0
Eyelid sensory disorder	5	0
Foreign body sensation in eyes	34	0
Hypoaesthesia eye	26	0
Photophobia	905	0
<i>Optic disc abnormalities NEC</i>		
Optic atrophy	1	0
Optic discs blurred	2	0
Papilloedema	9	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic disc haemorrhage	2	0
Optic ischaemic neuropathy	7	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	3	0
<i>Pupil disorders</i>		
Miosis	10	0
Mydriasis	27	0
Pupil fixed	10	0
Pupils unequal	10	0
<i>Refractive and accommodative disorders</i>		
Altered visual depth perception	5	0
Hypermetropia	1	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	10	0
Retinal infarction	1	0
Retinal vascular occlusion	2	0
Retinal vascular thrombosis	2	0
Retinal vein occlusion	57	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	6	0
Macular detachment	1	0
Macular hole	2	0
Neovascular age-related macular degeneration	10	0
Retinal detachment	19	0
Retinal drusen	1	0
Retinal tear	11	0
Retinal toxicity	3	0
Vitreoretinal traction syndrome	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Macular oedema	4	0
<i>Retinopathies NEC</i>		
Acute macular outer retinopathy	4	0
Acute zonal occult outer retinopathy	1	0
Retinal exudates	14	0

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Eye disorders Eye disorders cont'd		
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	1	0
Erythropsia	3	0
Xanthopsia	7	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0
Diplopia	269	0
Dysmetropsia	1	0
Halo vision	10	0
Metamorphopsia	28	0
Photopsia	273	0
Scintillating scotoma	5	0
Vision blurred	2340	0
Visual brightness	8	0
Visual snow syndrome	3	0
<i>Visual field disorders</i>		
Visual field defect	24	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	8	0
Blindness	221	0
Blindness transient	18	0
Blindness unilateral	23	0
Central vision loss	2	0
Night blindness	4	0
Sudden visual loss	5	0
Visual acuity reduced	27	0
Visual acuity reduced transiently	1	0
Visual impairment	559	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	2	0
Optic neuropathy	7	0
Eye disorders SOC TOTAL	11480	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	3	0
Gastrointestinal sounds abnormal	17	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	28	1
Pancreatitis acute	15	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	4	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	39	0
Colitis ischaemic	5	1
Colitis microscopic	4	0
Colitis ulcerative	72	0
Crohn's disease	66	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	19	0
Tooth disorder	2	0
Tooth socket haemorrhage	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	11	0
Dental paraesthesia	16	0
Hyperaesthesia teeth	47	0
Hypoaesthesia teeth	2	0
Toothache	278	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	14	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	10	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	7857	0
Diarrhoea haemorrhagic	29	0
<i>Diverticula</i>		
Diverticulum	9	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	747	0
Epigastric discomfort	18	0
Eructation	88	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	16	0
Faecaloma	2	0
Faeces discoloured	43	0
Faeces hard	4	0
Faeces pale	6	0
Faeces soft	18	0
Mucous stools	12	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	434	0
Flatulence	358	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	75	0
Reflux gastritis	15	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	3	0
Abdominal pain	3953	0
Abdominal pain lower	206	0
Abdominal pain upper	4519	0
Abdominal rigidity	49	0
Abdominal tenderness	18	0
Gastrointestinal pain	278	0
Oesophageal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	383	0
Duodenogastric reflux	2	0
Gastric dilatation	15	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastroesophageal reflux disease	182	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	11	0
Functional gastrointestinal disorder	9	0
Gastric disorder	8	0
Gastrointestinal disorder	23	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	14	0
Defaecation disorder	1	0
Dyschezia	13	0
Gastrointestinal motility disorder	2	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	1406	0
Abdominal symptom	5	0
Acute abdomen	13	0
Anal incontinence	35	0
Breath odour	22	0
Dysphagia	202	0
Intestinal congestion	1	0
Odynophagia	28	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	2	1
Defaecation urgency	12	0
Frequent bowel movements	38	0
Irritable bowel syndrome	107	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 vascular malformations		
Gastric antral vascular ectasia	7	0
Gastrointestinal vascular occlusion and infarction		
Intestinal infarction	3	0
Intestinal ischaemia	23	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	204	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	42	0
Gingival ulceration	8	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	20	0
Gingival haemorrhages		
Gingival bleeding	127	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	50	0
Haemorrhoids thrombosed	9	0
Inguinal hernias		
Inguinal hernia	3	0
Intestinal haemorrhages		
Anal haemorrhage	30	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	1	0
Rectal haemorrhage	91	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
Nausea and vomiting symptoms		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Acetonaemic vomiting	1	0
Discoloured vomit	17	0
Faecal vomiting	3	0
Infantile vomiting	2	0
Nausea	30861	0
Regurgitation	2	0
Retching	215	0
Vomiting	10330	3
Vomiting projectile	142	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	24	0
Haematemesis	69	0
Haematochezia	76	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	13	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	4	0
Dry mouth	1052	0
Lip dry	74	0
Saliva altered	6	0
Saliva discolouration	1	0
Salivary hypersecretion	69	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	2	0
Chapped lips	18	0
Cheilitis	32	0
Chronic cheek biting	1	0
Enlarged uvula	10	0
Leukoplakia oral	2	0
Lip blister	31	0
Lip disorder	4	0
Oral disorder	12	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	32	0
Oral blood blister	43	0
Oral purpura	2	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	9	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	7	0
Burning mouth syndrome	13	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Coating in mouth	4	0
Hypoaesthesia oral	552	0
Lip discolouration	1	0
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	51	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	80	0
Oral mucosal blistering	28	0
Oral mucosal eruption	24	0
Oral mucosal erythema	4	0
Oral mucosal exfoliation	8	0
Oral mucosal roughening	3	0
Oral pain	312	0
Oral pruritus	19	0
Paraesthesia oral	750	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	9	0
Lip swelling	840	0
Mouth swelling	107	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	1	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	5	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	11	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	8	0
Salivary gland enlargement	5	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	56	0
Lip ulceration	14	0
Mouth ulceration	657	0
Stomatitis	93	0
<i>Tongue disorders</i>		
Glossitis	15	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
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	231	0
Scalloped tongue	4	0
Stiff tongue	4	0
Strawberry tongue	1	0
Swollen tongue	536	0
Tongue blistering	25	0
Tongue coated	33	0
Tongue discolouration	29	0
Tongue discomfort	43	0
Tongue dry	19	0
Tongue eruption	7	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	4	0
Gastrointestinal disorders SOC TOTAL	70843	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	37	0
Administration site rash	2	0
Administration site reaction	5	0
Administration site swelling	3	0
Administration site urticaria	5	0
Administration site warmth	1	0
Puncture site bruise	55	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	43	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	9	0
Application site warmth	2	0
Application site wound	1	0
Instillation site bruise	1	0
Instillation site discomfort	1	0
Instillation site pain	4	0
Instillation site pruritus	1	0
Instillation site warmth	12	0
<i>Asthenic conditions</i>		
Asthenia	4221	3
Chronic fatigue syndrome	110	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Decreased activity	8	0
Fatigue	44657	0
Malaise	11185	3
Sluggishness	23	0
Body temperature altered		
Hyperthermia	9	0
Hypothermia	49	0
Temperature regulation disorder	25	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	252	252
Drowning	1	0
Sudden death	27	27
Febrile disorders		
Hyperpyrexia	40	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	51821	0
Feelings and sensations NEC		
Chills	41080	0
Early satiety	1	0
Feeling abnormal	2696	0
Feeling cold	4914	0
Feeling drunk	118	0
Feeling hot	2168	0
Feeling jittery	42	0
Feeling of body temperature change	891	0
Feeling of relaxation	1	0
Hangover	165	0
Hunger	69	0
Sensation of blood flow	13	0
Sensation of foreign body	42	0
Temperature intolerance	67	0
Thirst	1174	0
Thirst decreased	10	0
Fibrosis NEC		
Fibrosis	3	0
Gait disturbances		
Decreased gait velocity	3	0
Gait disturbance	331	0
Gait inability	165	0
Loss of control of legs	41	0
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	199	0
Crepitations	7	0
Crying	245	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Deformity	1	0
Developmental delay	4	0
Discharge	6	0
Disease progression	1	0
Disease recurrence	1	0
Effusion	1	0
Energy increased	21	0
Exercise tolerance decreased	27	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	4	0
Illness	4528	0
Induration	20	0
Influenza like illness	8887	1
Irritability postvaccinal	3	0
Local reaction	154	0
Moaning	8	0
Multiple organ dysfunction syndrome	16	6
Nonspecific reaction	3	0
Organ failure	1	0
Perforation	1	0
Peripheral swelling	5053	0
Pre-existing condition improved	11	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	2367	0
Swelling face	893	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	2	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	2	0
Implant site urticaria	1	0
Implant site warmth	7	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Inflamations</i>		
Granuloma	1	0
Inflammation	610	0
Systemic inflammatory response syndrome	3	0
<i>Infusion site reactions</i>		
Infusion site bruising	1	0
Infusion site erythema	2	0
Infusion site mass	2	0
Infusion site nodule	2	0
Infusion site pain	12	0
Infusion site urticaria	1	0
Infusion site warmth	6	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	33	0
Injection site atrophy	9	0
Injection site bruising	105	0
Injection site coldness	5	0
Injection site cyst	4	0
Injection site deformation	1	0
Injection site discharge	1	0
Injection site discolouration	5	0
Injection site discomfort	16	0
Injection site dryness	1	0
Injection site erythema	549	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	2	0
Injection site haemorrhage	13	0
Injection site hypersensitivity	4	0
Injection site hypoaesthesia	14	0
Injection site indentation	13	0
Injection site induration	8	0
Injection site inflammation	59	0
Injection site injury	4	0
Injection site irritation	3	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	1327	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	25	0
Injection site pain	4191	0
Injection site papule	2	0
Injection site paraesthesia	24	0
Injection site pruritus	276	0
Injection site rash	284	0
Injection site reaction	114	0
Injection site scab	4	0
Injection site scar	6	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site swelling	226	0
Injection site thrombosis	1	0
Injection site ulcer	1	0
Injection site urticaria	37	0
Injection site vesicles	11	0
Injection site warmth	334	0
Interactions		
Drug interaction	28	0
Inhibitory drug interaction	9	0
Mass conditions NEC		
Cyst	19	0
Mass	68	0
Nodule	16	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	4	0
Mucosal inflammation	8	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	58	0
Oedema peripheral	112	0
Pain and discomfort NEC		
Axillary pain	667	0
Chest discomfort	1776	0
Chest pain	4352	1
Discomfort	474	0
Facial discomfort	17	0
Facial pain	233	0
Hernia pain	2	0
Inflammatory pain	18	0
Non-cardiac chest pain	35	0
Pain	14755	0
Suprapubic pain	1	0
Tenderness	1744	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	87	1
Adverse event	22	0
Adverse reaction	44	0
Diet failure	1	0
Drug ineffective	132	0
Drug intolerance	4	0
Idiosyncratic drug reaction	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Immediate post-injection reaction	4	0
Inadequate analgesia	23	0
No reaction on previous exposure to drug	56	0
Remission not achieved	1	0
Similar reaction on previous exposure to drug	1	0
Therapeutic product effect decreased	2	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	110	0
Therapy non-responder	3	0
Treatment failure	6	0
Vaccination failure	24	0
Vaccine positive rechallenge	1	0
Trophic disorders		
Atrophy	3	0
Calcinosis	2	0
Dysplasia	2	0
Ulcers NEC		
Ulcer	37	0
Ulcer haemorrhage	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	17	0
Shoulder injury related to vaccine administration	36	0
Vaccination site atrophy	1	0
Vaccination site bruising	121	0
Vaccination site coldness	1	0
Vaccination site cyst	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	10	0
Vaccination site discomfort	41	0
Vaccination site dryness	1	0
Vaccination site erythema	649	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	66	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
Vaccination site joint movement impairment	10	0
Vaccination site joint pain	43	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site lymphadenopathy	2	0
Vaccination site mass	491	0
Vaccination site movement impairment	65	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	1840	0
Vaccination site papule	3	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	101	0
Vaccination site rash	166	0
Vaccination site reaction	22	0
Vaccination site scab	1	0
Vaccination site scar	5	0
Vaccination site swelling	459	0
Vaccination site urticaria	11	0
Vaccination site vesicles	9	0
Vaccination site warmth	354	0
<i>Vascular complications associated with device</i>		
Vascular stent occlusion	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	8	0
Withdrawal syndrome	80	0
General disorders SOC TOTAL	227588	298

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	26	0
Cholangitis	4	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	11	0
Cholelithiasis	10	0
<i>Cholestasis and jaundice</i>		
Cholestasis	5	0
Jaundice	42	0
Jaundice cholestatic	8	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	12	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	8	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	1	0
Portal vein phlebitis	1	0
Portal vein thrombosis	52	5
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	54	0
Hepatomegaly	3	0
Liver tenderness	5	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	20	0
Hepatitis acute	6	1
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0
Liver injury	17	0
Reye's syndrome	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	3	0
Hepatic disorders SOC TOTAL	337	8

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

Data Lock Date: 02-Jun-2021 18:30:03
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	1	0
Hypersensitivity	1214	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	1	0
Allergy to chemicals	6	0
Allergy to vaccine	46	0
Contrast media reaction	4	0
Drug hypersensitivity	59	0
Food allergy	21	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	595	2
Anaphylactic shock	104	0
Anaphylactoid reaction	21	0
Anaphylactoid shock	3	0
<i>Atopic disorders</i>		
Atopy	2	0
Seasonal allergy	74	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	31	0
<i>Endocrine autoimmune disorders</i>		
Hashitoxicosis	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	32	0
Cytokine release syndrome	1	0
Cytokine storm	3	0
Haemophagocytic lymphohistiocytosis	7	0
Immune system disorder	18	0
Immune-mediated adverse reaction	8	0
Immunisation reaction	1	0
Pre-engraftment immune reaction	1	0

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

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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	3	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	2441	2

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

Data Lock Date: 02-Jun-2021 18:30:03
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	26	0
Appendicitis perforated	3	0
Diarrhoea infectious	3	0
Diverticulitis	20	0
Dysentery	4	0
Gastroenteritis	32	0
Gastrointestinal infection	5	0
Large intestine infection	2	0
Peritonitis	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	4	0
Bacterial infection	26	1
Bacterial vaginosis	2	0
Cellulitis	460	1
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
Intervertebral discitis	2	0
Osteomyelitis	1	0
<i>Bordetella infections</i>		
Pertussis	3	0
<i>Borrelial infections</i>		
Erythema migrans	2	0
Lyme disease	7	0
Relapsing fever	1	0
<i>Breast infections</i>		
Mastitis	29	0
<i>Brucella infections</i>		
Brucellosis	1	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
<i>Campylobacter infections</i>		
Campylobacter colitis	1	0
<i>Candida infections</i>		
Anal candidiasis	1	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Balanitis candida	1	0
Candida infection	53	0
Oral candidiasis	43	0
Skin candida	2	0
Vulvovaginal candidiasis	42	0
Cardiac infections		
Endocarditis	2	0
Central nervous system and spinal infections		
Cavernous sinus thrombosis	5	0
Central nervous system infection	1	0
Encephalitis	31	0
Encephalomyelitis	2	0
Extradural abscess	1	0
Meningitis	23	0
Myelitis	11	0
Chlamydial infections		
Chlamydial infection	1	0
Clostridia infections		
Clostridium difficile colitis	3	0
Clostridium difficile infection	2	0
Tetanus	3	0
Coronavirus infections		
Asymptomatic COVID-19	4	0
COVID-19	417	23
COVID-19 pneumonia	23	7
Coronavirus infection	4	0
Post-acute COVID-19 syndrome	3	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	36	0
Corynebacteria infections		
Diphtheria	2	0
Coxiella infections		
Q fever	105	0
Dental and oral soft tissue infections		
Abscess oral	3	0
Gingival abscess	7	0
Gingivitis	23	0
Lip infection	1	0
Oral infection	1	0
Oral pustule	3	0
Parotitis	11	0
Pericoronitis	2	0
Periodontitis	1	0
Pulpitis dental	1	0
Sialoadenitis	2	0
Tongue abscess	3	0
Tooth abscess	13	0
Tooth infection	11	0
Ear infections		
Ear infection	88	0
Labyrinthitis	130	0
Mastoiditis	3	0
Otitis externa	3	0

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021
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Reaction Name	Total	Fatal
Infections Infections cont'd		
Otitis media	13	0
Otosalpingitis	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	2	0
Infestation	1	0
Trombidiasis	2	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	2	0
Infectious mononucleosis	44	0
<i>Escherichia infections</i>		
Escherichia infection	2	0
Escherichia sepsis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	68	0
Eye infection	24	0
Eyelid boil	3	0
Eyelid infection	3	0
Hordeolum	27	0
Keratouveitis	1	0
Retinitis	2	0
<i>Female reproductive tract infections</i>		
Endometritis	1	0
Pelvic inflammatory disease	1	0
Pyometra	1	1
Vaginal abscess	1	0
Vaginal infection	4	0
<i>Flaviviral infections</i>		
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1	0
<i>Fungal infections NEC</i>		
Ear infection fungal	1	0
Fungal infection	15	0
Fungal skin infection	6	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
<i>Hepatitis virus infections</i>		
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	5	1
<i>Herpes viral infections</i>		
Eczema herpeticum	3	0
Genital herpes	51	0
Genital herpes simplex	1	0
Haemorrhagic varicella syndrome	1	0
Herpes dermatitis	2	0
Herpes ophthalmic	14	0
Herpes simplex	33	0
Herpes simplex reactivation	2	0
Herpes virus infection	12	0
Herpes zoster	1140	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Herpes zoster oticus	10	0
Herpes zoster reactivation	2	0
Meningoencephalitis herpetic	1	0
Nasal herpes	15	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	8	0
Oral herpes	617	0
Varicella	32	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	30	0
Abscess limb	17	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	2	0
Infection	413	3
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	17	0
Localised infection	96	0
Lymph gland infection	3	0
Lymph node abscess	1	0
Omphalitis	1	0
Pathogen resistance	2	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
<i>Infectious disorders carrier</i>		
SARS-CoV-2 carrier	1	0
<i>Infectious transmissions</i>		
Secondary transmission	10	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
H2N2 influenza	2	0
Influenza	6242	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

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Lower respiratory tract infection	229	3
Pleural infection	1	0
Pneumonia	191	18
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	5	0
Orchitis	1	0
Mumps viral infections		
Mumps	7	0
Muscle and soft tissue infections		
Muscle abscess	2	0
Soft tissue infection	5	0
Orthopox viral infections		
Cow pox	1	0
Papilloma viral infections		
Papilloma viral infection	1	0
Paravaccinia infections		
Paravaccinia	1	0
Phleboviral infections		
Severe fever with thrombocytopenia syndrome	1	0
Plasmodia infections		
Malaria	6	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	1	0
Polyomavirus infections		
Progressive multifocal leukoencephalopathy	2	0
Prion-associated disorders		
Creutzfeldt-Jakob disease	4	0
Retroviral infections		
Acquired immunodeficiency syndrome	2	0
HIV-associated neurocognitive disorder	1	0
Rotaviral infections		
Rotavirus infection	1	0
Rubella viral infections		
Rubella	1	0
Rubeola viral infections		
Measles	4	0
Salmonella infections		
Typhoid fever	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Abdominal sepsis	1	0
Bacteraemia	1	0
Neutropenic sepsis	8	0
Sepsis	78	8
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	9	0
Septic shock	5	2
Urosepsis	6	1
Viraemia	3	0
Skin structures and soft tissue infections		
Carbuncle	1	0
Dermatitis infected	10	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Eczema infected	1	0
Impetigo	7	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	15	0
Rash pustular	17	0
Skin infection	60	0
Subcutaneous abscess	8	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	42	0
Staphylococcal bacteraemia	2	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	3	1
Toxic shock syndrome staphylococcal	2	0
Vulvovaginitis staphylococcal	1	0
Streptococcal infections		
Cellulitis streptococcal	1	0
Erysipelas	1	0
Pharyngitis streptococcal	7	0
Scarlet fever	1	0
Streptococcal infection	1	0
Tonsillitis streptococcal	1	0
Tinea infections		
Body tinea	3	0
Tinea cruris	1	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	1	0
Treponema infections		
Syphilis	3	0
Trypanosomal infections		
African trypanosomiasis	6	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Erythema induratum	1	0
Lymph node tuberculosis	3	0
Meningitis tuberculous	1	0
Pulmonary tuberculosis	2	0
Tuberculosis	4	0
Upper respiratory tract infections		
Acute sinusitis	4	0
Chronic sinusitis	13	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	24	0
Nasal vestibulitis	1	0
Nasopharyngitis	1600	0
Pharyngeal abscess	1	0
Pharyngitis	29	0
Rhinitis	44	0
Sinobronchitis	1	0
Sinusitis	301	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Tonsillitis	67	0
Tracheitis	1	0
Upper respiratory tract infection	6	0
Urinary tract infections		
Cystitis	77	0
Genitourinary tract infection	1	0
Kidney infection	43	0
Pyelonephritis	4	0
Pyelonephritis chronic	1	0
Renal abscess	1	0
Urinary tract infection	186	0
Vascular infections		
Haematoma infection	2	0
Infected lymphocele	1	0
Infected varicose vein	1	0
Lymphangitis	6	0
Viral infections NEC		
Arthritis viral	1	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	64	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	97	0
Sweating fever	709	0
Vestibular neuronitis	25	0
Viral diarrhoea	4	0
Viral infection	60	0
Viral labyrinthitis	6	0
Viral myocarditis	2	0
Viral pericarditis	1	0
Viral pharyngitis	28	0
Viral rash	70	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	15278	73

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021
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Data Lock Date: 02-Jun-2021 18:30:03
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	15	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	1	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 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	5	0
Cranio-cerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	1
Subdural haemorrhage	3	0
<i>Chemical injuries</i>		
Chemical burn	1	0
Chemical burn of oral cavity	1	0
Chemical burn of skin	4	0
Chemical phlebitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	11	0

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Chest injury	1	0
Foreign body in throat	1	0
Traumatic haemothorax	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	63	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	42	0
Foetal exposure during pregnancy	39	0
Maternal exposure during breast feeding	1054	0
Maternal exposure during pregnancy	228	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	4	0
Paternal exposure during pregnancy	17	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	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	27	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	8	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
Heat stroke	7	0
Intentional product misuses		
Intentional product misuse	4	0

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021
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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Intentional product use issues</i>		
Intentional product use issue	1	0
<i>Limb fractures and dislocations</i>		
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
<i>Medication errors, product use errors and issues NEC</i>		
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	3	0
Medication error	51	0
Prescription drug used without a prescription	1	0
Product use issue	3	0
Vaccination error	6	0
Wrong device used	1	0
Wrong drug	5	0
Wrong schedule	1	0
Wrong technique in product usage process	7	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	14	0
Ligament injury	3	0
Ligament rupture	1	0
Ligament sprain	17	0
Muscle injury	30	0
Muscle rupture	14	0
Muscle strain	38	0
Post-traumatic neck syndrome	3	0
Repetitive strain injury	2	0
Tendon injury	3	0
Tendon rupture	13	0
<i>Nerve injuries NEC</i>		
Nerve injury	90	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	8	0
Procedural dizziness	31	0
<i>Non-occupational environmental exposures</i>		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	2	0
<i>Non-site specific injuries NEC</i>		
Animal bite	1	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Arthropod bite	4	0
Arthropod sting	11	0
Bite	1	0
Electric shock	25	0
Fall	209	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	1	0
Tissue injury	1	0
Traumatic haematoma	3	0
Traumatic shock	1	0
Wound	7	0
Wound complication	12	0
Wound haemorrhage	9	0
Wound secretion	2	0
Non-site specific procedural complications		
Administration related reaction	1	0
Incision site erythema	1	0
Incision site haemorrhage	1	0
Incision site oedema	1	0
Incision site pain	9	0
Infusion related reaction	20	0
Injection related reaction	593	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	14	0
Overdoses NEC		
Intentional overdose	5	0
Overdose	20	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
Ulnar nerve injury	2	0
Poisoning and toxicity		
Alcohol poisoning	3	0
Chemical poisoning	1	0

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
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	2	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	15	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	23	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	12	0
Product administered to patient of inappropriate age	14	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	1	0
Product dispensing errors and issues		
Product dispensing error	12	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	8	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	2	0
Radiation injuries		
Sunburn	40	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Kidney rupture	1	0
Reproductive system and breast injuries		
Penile contusion	2	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		

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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	7	0
Limb injury	203	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	2511	0
Nail injury	1	0
Scar	19	0
Scratch	3	0
Skin abrasion	5	0
Skin injury	14	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	4	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	9	0
Burns second degree	7	0
Cold burn	3	0
Thermal burn	46	0
Thermal burns of eye	42	0
Transplantation complications		
Transplant failure	1	0
Underdoses NEC		
Intentional underdose	1	0
Underdose	3	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<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	91	0
Injuries SOC TOTAL	6517	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
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	2	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	4	0
Blood pH	13	0
Blood pH increased	12	0
Carbon dioxide increased	1	0
Oxygen consumption	1	0
Oxygen saturation	23	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	166	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	16	0
Blood glucose decreased	35	0
Blood glucose fluctuation	28	0
Blood glucose increased	166	0
Glycosylated haemoglobin increased	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	22	0
Heart sounds	15	0
Heart sounds abnormal	7	0
<i>Cardiac function diagnostic procedures</i>		
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
<i>Cardiac imaging procedures</i>		
Magnetic resonance imaging heart	1	0
<i>Cell marker analyses</i>		
Carcinoembryonic antigen increased	1	0
Prostatic specific antigen	1	0
Prostatic specific antigen increased	2	0
<i>Central nervous system histopathology procedures</i>		
Biopsy brain	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	17	0
Magnetic resonance imaging head	39	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF pressure	4	0
CSF white blood cell count increased	1	0
<i>Chemistry analyses NEC</i>		
Histamine abnormal	2	0
Histamine level	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	5	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	6	0
Low density lipoprotein	1	0
Low density lipoprotein increased	1	0
Very low density lipoprotein decreased	1	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time prolonged	107	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	3	0
Coagulation time	6	0
Coagulation time prolonged	11	0
Coagulation time shortened	3	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Fibrin D dimer	1	0
Fibrin D dimer decreased	1	0
Fibrin D dimer increased	37	0
International normalised ratio	2	0
International normalised ratio abnormal	10	0
International normalised ratio decreased	38	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	79	0
Prothrombin level increased	1	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
Pancreatic enzymes increased	1	0
<i>ECG investigations</i>		
Cardiac telemetry	1	0
Electrocardiogram	4	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	13	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	22	0
<i>Faecal analyses NEC</i>		
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 decreased	2	0
Blood insulin increased	3	0
<i>Haematological analyses NEC</i>		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Haematology test abnormal	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate	1	0
Red blood cell sedimentation rate increased	5	0
Heart rate and pulse investigations		
Brachial pulse decreased	1	0
Heart rate	965	0
Heart rate abnormal	47	0
Heart rate decreased	106	0
Heart rate increased	1855	0
Heart rate irregular	157	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	23	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
Immune response protein analyses NEC		
C1 esterase inhibitor test	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	4	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
Blood test abnormal	47	0
Laboratory test	1	0
Polymerase chain reaction positive	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Liver function analyses</i>		
Alanine aminotransferase increased	16	0
Aspartate aminotransferase increased	3	0
Bile output	3	0
Blood bilirubin	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	11	0
Liver function test	3	0
Liver function test abnormal	30	0
Liver function test increased	6	0
Transaminases increased	9	0
<i>Metabolism tests NEC</i>		
Blood ketone body	9	0
Blood uric acid increased	1	0
Ubiquinone	3	0
Ubiquinone decreased	2	0
Urine ketone body present	1	0
<i>Microbiology and serology tests NEC</i>		
Blood culture	2	0
Blood culture negative	1	0
Septic screen	1	0
<i>Mineral and electrolyte analyses</i>		
Blood calcium	1	0
Blood calcium increased	1	0
Blood cyanide	1	0
Blood iron	10	0
Blood iron decreased	7	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
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Bone densitometry	1	0
Skull X-ray	7	0
X-ray of pelvis and hip	1	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count	2	0
Swollen joint count increased	2	0
Tender joint count	3	0
<i>Mycobacteria identification and serology</i>		
Interferon gamma release assay positive	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Tuberculin test	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	15	0
Electromyogram abnormal	1	0
Joint position sense decreased	1	0
Lumbar puncture	12	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	2	0
Intraocular pressure increased	3	0
Intraocular pressure test	8	0
Visual tracking test	1	0
Physical examination procedures and organ system status		
Body height decreased	1	0
Body surface area	2	0
Body temperature	974	0
Body temperature abnormal	76	0
Body temperature decreased	127	0
Body temperature fluctuation	171	0
Body temperature increased	1060	0
Body temperature normal	3	0
Breath sounds	1	0
Breath sounds abnormal	5	0
Dermatologic examination abnormal	1	0
General physical condition abnormal	3	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	1	0
Muscle strength abnormal	3	0
Neurological examination	1	0
Neurological examination normal	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	23	0
Respiratory rate increased	75	0
Skin temperature	167	0
Temperature difference of extremities	6	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	144	0
Weight increased	30	0
Pituitary analyses anterior		
Blood corticotrophin	1	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone	1	0
Blood thyroid stimulating hormone decreased	3	0
Blood thyroid stimulating hormone increased	4	0
Platelet analyses		
Platelet count	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Platelet count abnormal	1	0
Platelet count decreased	238	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	17	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	11	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
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	1	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	11	0
Pregnancy test false positive	1	0
Pregnancy test negative	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	1	0
Reproductive organ and breast imaging procedures		
Mammogram	1	0
Ultrasound scan vagina normal	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume	2	0
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	11	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	6	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	15	0
Computerised tomogram thorax	4	0
Laryngoscopy	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	5	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
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
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0
Thyroxine	1	0
Thyroxine abnormal	1	0
Tri-iodothyronine decreased	6	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	1	0
Blood heavy metal test	1	0
Blood lead	1	0
Drug screen positive	3	0
Urinalysis NEC		
Blood urine	28	0
Blood urine present	66	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Urine analysis	1	0
Urine analysis abnormal	12	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	42	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	261	0
Blood pressure measurement	88	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	14	0
SARS-CoV-2 antibody test positive	3	0
SARS-CoV-2 test	18	0
SARS-CoV-2 test false negative	4	0
SARS-CoV-2 test false positive	3	0
SARS-CoV-2 test negative	15	0
SARS-CoV-2 test positive	85	0
Viral test	4	0
Vitamin analyses		
Blood folate	2	0
Blood folate decreased	4	0
Vitamin B12 decreased	1	0
Vitamin D decreased	3	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Water and electrolyte analyses NEC</i>		
Blood osmolarity	1	0
Volume blood	6	0
<i>White blood cell analyses</i>		
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	12	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	14	0
White blood cell count decreased	24	0
White blood cell count increased	8	0
Investigations SOC TOTAL	9047	2

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	37	0
Decreased appetite	6001	1
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	20	0
Food refusal	35	0
Hyperphagia	7	0
Hypophagia	26	0
Increased appetite	54	0
Salt craving	4	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	2	0
Hypocalcaemia	5	0
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	80	0
Diabetes mellitus inadequate control	27	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	17	0
Type 2 diabetes mellitus	2	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	31	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	126	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	48	0
Abnormal weight gain	21	0
Cachexia	2	0
Feeding disorder	176	0
Food aversion	55	0
Neonatal insufficient breast milk syndrome	3	0
Obesity	1	0

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Report Run Date: 03-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	1	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	90	0
Hypoglycaemia unawareness	3	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	6	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	19	0
Hyponatraemic syndrome	3	1
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	6	0
Total fluid volume decreased		
Dehydration	610	0
Hypovolaemia	1	0
Total fluid volume increased		
Fluid overload	6	0
Fluid retention	55	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	7854	7

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	360	0
Arthritis enteropathic	1	0
Arthropathy	25	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	2	0
Bone erosion	1	0
Bone loss	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	941	0
Bone swelling	5	0
Coccydynia	5	0
Pain in jaw	528	0
Pubic pain	1	0
Spinal pain	221	0
<i>Bursal disorders</i>		
Bursitis	103	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	53	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	2	0
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	56	0
Reynold's syndrome	5	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
<i>Fractures NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Osteoporotic fracture	2	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc degeneration	2	0
Intervertebral disc protrusion	3	0
<i>Joint related disorders NEC</i>		
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	41	0
Ligament laxity	1	0
Patellofemoral pain syndrome	4	0
Periarthritis	250	0
Rotator cuff syndrome	51	0
Temporomandibular joint syndrome	15	0
<i>Joint related signs and symptoms</i>		
Arthralgia	20385	0
Jaw clicking	4	0
Joint effusion	3	0
Joint noise	38	0
Joint range of motion decreased	3	0
Joint stiffness	368	0
Joint swelling	709	0
Joint vibration	4	0
Joint warmth	27	0
Loose body in joint	1	0
<i>Ligament disorders</i>		
Ligament pain	10	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	29	0
<i>Metabolic bone disorders</i>		
Dwarfism	1	0
Osteopenia	2	0
Osteoporosis	10	0
<i>Muscle infections and inflammations</i>		
Myositis	28	0
Polymyositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	226	0
Myalgia	24779	0
Myalgia intercostal	2	0
Myofascial pain syndrome	20	0
<i>Muscle related signs and symptoms NEC</i>		
Haematoma muscle	3	0
Muscle atrophy	21	0
Muscle discomfort	12	0
Muscle disorder	7	0
Muscle fatigue	861	0
Muscle haemorrhage	3	0
Muscle mass	7	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Muscle oedema	2	0
Muscle spasms	2537	0
Muscle swelling	26	0
Muscle tightness	167	0
Muscle twitching	413	0
Muscle tone abnormalities		
Muscle rigidity	48	0
Nuchal rigidity	14	0
Torticollis	8	0
Trismus	50	0
Muscle weakness conditions		
Muscular weakness	1710	0
Musculoskeletal and connective tissue conditions NEC		
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	1967	0
Posture abnormal	1	0
Somatic dysfunction	1	0
Weight bearing difficulty	6	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	3	0
Head deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	2	0
Dactylitis	2	0
Fasciitis	1	0
Plantar fasciitis	7	0
Musculoskeletal and connective tissue pain and discomfort		
Amplified musculoskeletal pain syndrome	1	0
Back pain	5117	0
Flank pain	66	0
Growing pains	8	0
Limb discomfort	2006	0
Musculoskeletal chest pain	365	0
Musculoskeletal discomfort	116	0
Musculoskeletal pain	62	0
Neck pain	2656	0
Pain in extremity	18952	0
Rheumatic disorder	16	0
Myopathies		
Compartment syndrome	3	0
Muscle necrosis	1	0
Myopathy	4	0
Rhabdomyolysis	7	1
Osteoarthropathies		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	43	0
Spinal osteoarthritis	4	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	24	0
<i>Rheumatoid arthropathies</i>		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	136	0
Rheumatoid nodule	1	0
Still's disease	4	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	55	0
Clubbing	1	0
Fistula	2	0
Groin pain	179	0
Neck mass	19	0
Soft tissue disorder	1	0
Soft tissue mass	3	0
Soft tissue swelling	5	0
<i>Spine and neck deformities</i>		
Kyphosis	5	0
Scoliosis	2	0
Spinal stenosis	2	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	27	0
Arthritis reactive	28	0
Axial spondyloarthritis	1	0
Spondylitis	4	0
<i>Synovial disorders</i>		
Synovial cyst	6	0
Synovitis	12	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon discomfort	4	0
Tendon disorder	6	0
Tendon pain	31	0
Tendonitis	54	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	1	0
Trigger finger	19	0
Muscle & tissue disorders SOC TOTAL	87500	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 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	1	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>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>		
Leukaemia	1	0
Leukaemia recurrent	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	6	0

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

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	7	0
Ovarian cancer recurrent	1	0
Ovarian cancer stage IV	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	3	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
<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	11	0
Melanocytic naevus	2	0
Skin papilloma	15	0
<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

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<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	280	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	2	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	23	0
<i>Absence seizures</i>		
Petit mal epilepsy	28	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	3	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	283	4
Miller Fisher syndrome	16	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 dissection	1	0
Intracranial aneurysm	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	8	0
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	135	35
Cerebral infarction	68	3
Cerebral ischaemia	3	0
Cerebral thrombosis	32	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	868	36
Embolic stroke	19	0
Haemorrhage intracranial	43	7
Haemorrhagic cerebral infarction	3	1
Haemorrhagic stroke	31	4

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
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	103	3
Lacunar infarction	4	0
Lacunar stroke	19	0
Spinal cord haematoma	1	0
Spinal stroke	1	0
Subarachnoid haemorrhage	92	5
Thalamus haemorrhage	6	0
Thrombotic stroke	10	0
Vertebral artery occlusion	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	3	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	1	0
Cerebrovascular disorder	3	0
Internal carotid artery deformity	1	0
Reversible cerebral vasoconstriction syndrome	2	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	173	19
Cerebral venous thrombosis	36	4
Superior sagittal sinus thrombosis	26	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
Coma states		
Coma	12	0
Diabetic coma	3	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	29	0
Balance disorder	708	0

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Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021
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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cerebellar ataxia	1	0
Coordination abnormal	104	0
Dysdiadochokinesis	1	0
Dysstasia	91	0
Hand-eye coordination impaired	1	0
Nystagmus	19	0
Cortical dysfunction NEC		
Agraphia	1	0
Alexia	4	0
Aphasia	113	0
Apraxia	1	0
Dysgraphia	6	0
Dyslexia	2	0
Dyspraxia	4	0
Neurologic neglect syndrome	3	0
Visuospatial deficit	2	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Neurovascular conflict	1	0
Paresis cranial nerve	2	0
Dementia (excl Alzheimer's type)		
Dementia	19	0
Dementia with Lewy bodies	1	0
Frontotemporal dementia	1	0
Senile dementia	1	0
Vascular dementia	4	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	8	0
Demyelination	15	0
Neuromyelitis optica spectrum disorder	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	12	0
Consciousness fluctuating	4	0
Depressed level of consciousness	76	0
Lethargy	4340	0
Loss of consciousness	918	0
Postictal state	1	0
Sedation	12	0
Somnolence	1668	1
Stupor	8	0
Syncope	2199	0
Disturbances in sleep phase rhythm		
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
Dyskinesias and movement disorders NEC		
Akathisia	10	0
Ballismus	1	0
Bradykinesia	27	0
Clumsiness	41	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dyskinesia	96	0
Extrapyramidal disorder	18	0
Fine motor delay	3	0
Fine motor skill dysfunction	11	0
Hyperkinesia	26	0
Hypokinesia	55	0
Meige's syndrome	1	0
Motor dysfunction	13	0
Movement disorder	70	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		
Noninfective encephalitis	4	0
Encephalopathies NEC		
Autoimmune encephalopathy	3	0
Encephalopathy	5	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	2	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	391	0
Facial nerve disorder	4	0
Facial paralysis	230	0
Facial paresis	120	0
Facial spasm	28	0
Oculofacial paralysis	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	71	0
Headaches NEC		
Cervicogenic headache	5	0
Cluster headache	632	0
Cold-stimulus headache	70	0
Drug withdrawal headache	15	0
Exertional headache	10	0
External compression headache	4	0
Headache	73776	4
Medication overuse headache	14	0
New daily persistent headache	18	0
Occipital neuralgia	17	0
Ophthalmoplegic migraine	1	0
Post-traumatic headache	3	0
Primary cough headache	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Primary headache associated with sexual activity	11	0
Sinus headache	864	0
Tension headache	1318	0
Thunderclap headache	42	0
Vascular headache	68	0
Hydrocephalic conditions		
Hydrocephalus	9	0
Hypoglossal nerve disorders		
Tongue paralysis	5	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	22	1
Cerebrospinal fluid circulation disorder	3	0
Idiopathic intracranial hypertension	5	0
Intracranial pressure increased	20	0
Intellectual disabilities		
Intellectual disability	9	0
Lumbar spinal cord and nerve root disorders		
Lumbar radiculopathy	2	0
Sciatica	155	0
Memory loss (excl dementia)		
Amnesia	253	0
Memory impairment	234	0
Transient global amnesia	17	0
Meningitis NEC		
Meningitis noninfective	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	138	1
Disturbance in attention	571	0
Judgement impaired	3	0
Mental impairment	105	0
Migraine headaches		
Basilar migraine	4	0
Hemiplegic migraine	33	0
Migraine	6433	0
Migraine with aura	302	0
Migraine without aura	40	0
Ophthalmic migraine	9	0
Retinal migraine	63	0
Status migrainosus	5	0
Typical aura without headache	14	0
Vestibular migraine	22	0
Mixed cranial nerve disorders		
Bulbar palsy	1	0
Mononeuropathies		
Carpal tunnel syndrome	21	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	2	0
Nerve compression	40	0
Peroneal nerve palsy	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
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	7	0
Myelitis (incl infective)		
Myelitis transverse	63	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	169	0
Narcolepsy	14	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	1	0
Nervous system disorder	38	0
Neurotoxicity	1	0
Psychomotor skills impaired	4	0
Neurologic visual problems NEC		
Hemianopia	7	0
Hemianopia homonymous	1	0
Tunnel vision	15	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	19657	0
Dizziness exertional	84	0
Dizziness postural	1936	1
Drooling	20	0
Exaggerated startle response	3	0
Fontanelle bulging	3	0
Head discomfort	567	0
Hyporesponsive to stimuli	2	0
Inability to crawl	1	0
Infant irritability	5	0
Intracranial hypotension	2	0
Meningism	2	0
Myoclonus	25	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neurological decompensation	4	0
Neurological symptom	87	0
Patient elopement	2	0
Persistent postural-perceptual dizziness	29	0
Pleocytosis	3	0
Presyncope	538	0
Sensory overload	11	0
Slow response to stimuli	5	0
Tongue biting	8	0
Unresponsive to stimuli	81	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	29	0
Muscle spasticity	23	0
Neuromuscular pain	6	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	9	0
Myasthenia gravis crisis	3	0
Olfactory nerve disorders		
Anosmia	256	0
Hyposmia	10	0
Parosmia	333	0
Optic nerve disorders NEC		
Optic neuritis	36	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	22	0
Burning sensation	757	0
Burning sensation mucosal	3	0
Dysaesthesia	7	0
Formication	58	0
Hand-arm vibration syndrome	1	0
Hemianaesthesia	3	0
Hemiparaesthesia	2	0
Hyperaesthesia	239	0
Hypoaesthesia	4596	0
Lhermitte's sign	1	0
Paraesthesia	7726	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	24	0
Hemiparesis	82	0
Hemiplegia	25	0
Monoparesis	79	0
Monoplegia	107	0
Paralysis	251	0
Paraparesis	6	0
Paraplegia	2	0
Paresis	5	0
Peripheral nerve palsy	1	0
Postictal paralysis	1	0
Quadriplegia	3	0
Parkinson's disease and parkinsonism		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Freezing phenomenon	148	0
Parkinson's disease	15	0
Parkinsonism	10	0
Reduced facial expression	6	0
Vascular parkinsonism	1	0
Partial complex seizures		
Dreamy state	19	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	5	0
Neuritis	10	0
Neuropathy peripheral	157	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
Drug withdrawal convulsions	2	0
Epilepsy	246	0
Epileptic aura	2	0
Febrile convulsion	87	0
Migraine-triggered seizure	1	0
Myoclonic epilepsy	4	0
Partial seizures	50	0
Psychogenic seizure	5	0
Seizure	1054	2
Seizure anoxic	3	0
Seizure cluster	6	0
Seizure like phenomena	2	0
Status epilepticus	114	3
Tonic clonic movements	2	0
Tonic convulsion	32	0
Sensory abnormalities NEC		
Ageusia	929	0
Allodynia	55	0
Aura	21	0
Central pain syndrome	2	0
Complex regional pain syndrome	8	0
Dysgeusia	1817	0
Electric shock sensation	78	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Hypogeusia	5	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Neuralgia	1051	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	327	0
Sensory disturbance	97	0
Sensory loss	170	0
Taste disorder	446	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	317	0
Incoherent	15	0
Language disorder	2	0
Muscle tension dysphonia	1	0
Slow speech	28	0
Speech disorder	70	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	4	0
Myelopathy	3	0
Radicular pain	1	0
Radiculitis brachial	12	0
Radiculopathy	2	0
Spinal cord disorder	3	0
Spinal cord oedema	1	0
Structural brain disorders NEC		
Brain injury	21	1
Cerebral mass effect	5	0
Intracranial mass	3	0
White matter lesion	1	0
Transient cerebrovascular events		
Transient ischaemic attack	365	0
Tremor (excl congenital)		
Action tremor	2	0
Asterixis	1	0
Essential tremor	5	0
Head titubation	15	0
Intention tremor	1	0
Postural tremor	1	0
Resting tremor	5	0
Tremor	9074	3
Trigeminal disorders		
Facial neuralgia	31	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Trigeminal neuralgia	69	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	154901	152

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	80	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>High risk pregnancies</i>		
Pregnancy with young maternal age	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>		
Ectopic pregnancy	3	0
Hyperemesis gravidarum	2	0
Morning sickness	36	0
Pelvic girdle pain	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Pregnancy	21	0
Uterine contractions during pregnancy	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	5	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	0
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	5	0
Pregnancy conditions SOC TOTAL	184	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	2	0
Device leakage	2	0
<i>Device malfunction events NEC</i>		
Oversensing	24	0
Stent malfunction	1	0
Thrombosis in device	37	0
Undersensing	3	0
<i>Device physical property and chemical issues</i>		
Needle issue	7	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	106	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	15	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	15	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	175	0
Anxiety	894	0
Immunisation anxiety related reaction	1	0
Nervousness	543	0
Procedural anxiety	1	0
Stress	96	0
Tension	58	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	13	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	10	0
Antisocial behaviour	1	0
Asocial behaviour	1	0
Aversion	1	0
Disinhibition	1	0
Impatience	2	0
Indifference	8	0
Paranoia	36	0
Personality change	5	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	402	0
<i>Communications disorders</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Communication disorder	3	0
Mutism	4	0
Speech sound disorder	2	0
Confusion and disorientation		
Confusional state	1752	1
Disorientation	634	0
Decreased physical activity levels		
Catatonia	2	0
Deliria		
Delirium	440	0
Delirium febrile	3	0
Delusional disorders		
Alice in wonderland syndrome	3	0
Delusional symptoms		
Delusion	41	0
Delusion of parasitosis	1	0
Mixed delusion	1	0
Thought withdrawal	1	0
Depressive disorders		
Agitated depression	3	0
Depression	479	0
Depression suicidal	13	0
Major depression	21	0
Mixed anxiety and depressive disorder	2	0
Dissociative states		
Depersonalisation/derealisation disorder	15	0
Dissociation	61	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	36	0
Insomnia	2723	0
Middle insomnia	69	0
Terminal insomnia	11	0
Dyssomnias		
Dyssomnia	4	0
Poor quality sleep	596	0
Eating disorders NEC		
Eating disorder	7	0
Pica	1	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	67	0
Dysphoria	2	0
Emotional disorder	82	0
Emotional distress	61	0
Emotional poverty	2	0
Euphoric mood	58	0
Frustration tolerance decreased	5	0
Irritability	265	0
Mood altered	60	0
Factitious disorders		
Factitious disorder	4	0

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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	34	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	2	0
Phobia	2	0
Phonophobia	3	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	70	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	848	0
Hallucination, auditory	38	0
Hallucination, olfactory	8	0
Hallucination, tactile	1	0
Hallucination, visual	52	0
Hallucinations, mixed	8	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	440	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
Emotional disorder of childhood	1	0
<i>Mental disorders NEC</i>		
Mental disorder	12	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	3	0
Decreased interest	12	0
Depressed mood	506	0
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	16	0
Negative thoughts	8	0
Sense of a foreshortened future	1	0
Tearfulness	95	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	29	0
<i>Mood disorders NEC</i>		
Affective disorder	3	0
Apathy	48	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Laziness	1	0
Listless	117	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	1	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	253	0
Panic disorder	3	0
Panic reaction	31	0
<i>Paraphilias and paraphilic disorders</i>		
Fetishism	2	0
<i>Parasomnias</i>		
Abnormal dreams	335	0
Abnormal sleep-related event	1	0
Confusional arousal	2	0
Exploding head syndrome	6	0
Nightmare	412	0
Parasomnia	1	0
Rapid eye movements sleep abnormal	3	0
Sleep inertia	1	0
Sleep talking	16	0
Sleep terror	55	0
Sleep-related eating disorder	2	0
Somnambulism	9	0
<i>Perception disturbances NEC</i>		
Autoscopy	21	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	3	0
Psychotic disorder NEC		
Acute psychosis	4	0
Psychotic behaviour	2	0
Psychotic disorder	33	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	33	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	1	0
Sleep disorders NEC		
Sleep disorder	339	0
Sleep disorder due to general medical condition, insomnia type	2	0
Somatic symptom disorders		
Conversion disorder	15	0
Habit cough	31	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	24	0
Lack of spontaneous speech	2	0
Stereotypies and automatisms		
Bruxism	29	0
Head banging	37	0
Waxy flexibility	2	0
Stress disorders		
Acute stress disorder	2	0
Burnout syndrome	11	0
Hyperarousal	3	0
Post-traumatic stress disorder	11	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	91	0
Suicide attempt	17	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	78	0
Confabulation	1	0
Impaired reasoning	3	0
Intrusive thoughts	3	0
Morbid thoughts	4	0
Tachyphrenia	22	0
Thinking abnormal	23	0
Thought blocking	4	0
<i>Tic disorders</i>		
Tic	9	0
Psychiatric disorders SOC TOTAL	14510	3

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	7	0
Bladder irritation	6	0
Bladder pain	48	0
Bladder spasm	1	0
Dysuria	69	0
Incontinence	66	0
Micturition disorder	3	0
Micturition frequency decreased	1	0
Micturition urgency	93	0
Mixed incontinence	1	0
Pollakiuria	251	0
Urethral pain	4	0
Urge incontinence	2	0
Urinary hesitation	5	0
Urinary incontinence	102	0
Urinary retention	65	0
Urine flow decreased	12	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	15	0
Urinary bladder haemorrhage	8	1
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	5	0
Cystitis noninfective	3	0
Lupus cystitis	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	5	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	1	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	12	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	2	0
<i>Renal disorders NEC</i>		
Oedematous kidney	1	0
Renal disorder	7	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal haemorrhage	1	0
Renal failure and impairment		
Acute kidney injury	46	1
Anuria	5	0
Chronic kidney disease	8	0
Oliguria	10	0
Renal failure	20	3
Renal impairment	12	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	10	0
Renal tubular injury	1	0
Renal vein embolism	1	0
Renal vein occlusion	1	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	89	0
Glycosuria	1	0
Haematuria	52	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	39	0
Nocturia	17	0
Polyuria	29	0
Renal colic	2	0
Renal pain	838	0
Urinary tract discomfort	1	0
Urinary tract pain	12	0
Renal & urinary disorders SOC TOTAL	2125	5

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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	38	0
Gynaecomastia	7	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	343	0
Breast swelling	48	0
Breast tenderness	44	0
Nipple exudate bloody	1	0
Nipple pain	30	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	2	0
Erectile dysfunction	53	0
Erection increased	4	0
Organic erectile dysfunction	17	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	21	0
<i>Menopausal effects NEC</i>		
Artificial menopause	2	0
Menopausal disorder	2	0
Menopausal symptoms	26	0
Menopause delayed	3	0
Premature menopause	8	0
<i>Menopausal effects on the genitourinary tract</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Postmenopausal haemorrhage	155	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	4	0
Abnormal withdrawal bleeding	4	0
Dysmenorrhoea	325	0
Intermenstrual bleeding	236	0
Menstrual discomfort	3	0
Menstrual disorder	461	0
Menstruation irregular	603	0
Premenstrual headache	2	0
Premenstrual pain	21	0
Premenstrual syndrome	10	0
Retrograde menstruation	1	0
Withdrawal bleed	9	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	166	0
Hypomenorrhoea	141	0
Menstruation delayed	792	0
Oligomenorrhoea	32	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	1309	0
Menometrorrhagia	7	0
Polymenorrhoea	182	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	10	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	13	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	14	0
Premature ovulation	2	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	23	0
Pelvic haematoma	1	0
Pelvic haemorrhage	10	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
Penile oedema	3	0
Penile pain	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Penile size reduced	1	0
Penis disorder	6	0
Peyronie's disease	4	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	4	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatism	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Female genital tract fistula	1	0
Genital blister	3	0
Genital haemorrhage	14	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
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	2	0
<i>Reproductive tract neoplasms NEC</i>		
Genital cyst	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
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	114	0
Perineal pain	1	0
Pruritus genital	6	0
<i>Scrotal disorders NEC</i>		
Scrotal dermatitis	1	0
Scrotal oedema	1	0
Scrotal pain	11	0
Scrotal swelling	5	0
Varicocele	1	0
<i>Sexual function and fertility disorders NEC</i>		
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
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haemospermia	7	0
Semen discolouration	2	0
<i>Testicular and epididymal disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Testicular atrophy	1	0
Testicular disorder	5	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	88	0
Testicular retraction	1	0
Testicular swelling	13	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	4	0
Endometriosis	35	0
Metrorrhoea	1	0
Uterine enlargement	1	0
Uterine haemorrhage	34	0
Uterine pain	6	0
<i>Uterine neoplasms</i>		
Uterine cyst	1	0
Uterine polyp	3	0
<i>Uterine tone disorders</i>		
Uterine spasm	11	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	10	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal disorder	1	0
Vaginal haemorrhage	556	0
Vaginal ulceration	6	0
Vulval disorder	2	0
Vulval haemorrhage	16	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	43	0
Vaginal lesion	4	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	7	0
Vulvovaginal discomfort	7	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	24	0
Vulvovaginal pruritus	7	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Reproductive & breast disorders SOC TOTAL	6454	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	12	0
Apnoeic attack	1	0
Dyspnoea	5910	5
Dyspnoea at rest	14	0
Dyspnoea exertional	36	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	84	0
Hypopnoea	196	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	7	0
Orthopnoea	3	0
Respiration abnormal	87	0
Respiratory arrest	19	0
Respiratory distress	9	0
Respiratory fatigue	6	0
Sleep apnoea syndrome	26	0
Tachypnoea	34	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	15	0
<i>Bronchospasm and obstruction</i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	490	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	31	2
Cough variant asthma	6	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	520	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Hypercapnia	1	0
Hypoxia	59	1
<i>Coughing and associated symptoms</i>		
Allergic cough	8	0
Cough	3354	0
Haemoptysis	102	0
Productive cough	160	0
Sputum discoloured	9	0
Sputum increased	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	2	0
Vocal cord thickening	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	2	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Laryngospasm	2	0
Stridor	19	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	2	0
Eosinophilic pneumonia	1	0
Pneumonia aspiration	22	4
Pneumonitis	21	1
Pulmonary sarcoidosis	2	0
Lower respiratory tract signs and symptoms		
Hiccups	39	0
Lower respiratory tract congestion	4	0
Lung opacity	5	0
Pleuritic pain	31	0
Pulmonary haemorrhage	5	1
Pulmonary pain	186	0
Rales	2	0
Mediastinal disorders		
Pulmonary hilum mass	1	0
Nasal congestion and inflammations		
Nasal congestion	414	0
Nasal inflammation	8	0
Rhinitis allergic	22	0
Rhinitis perennial	1	0
Nasal disorders NEC		
Epistaxis	1825	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	11	0
Nasal polyps	1	0
Nasal pruritus	8	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	3	0
Neonatal hypoxic conditions		
Cyanosis neonatal	1	0
Gasping syndrome	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	2	0
Sinonasal obstruction	9	0
Sinus congestion	75	0
Sinus disorder	12	0
Sinus polyp	1	0
Parenchymal lung disorders NEC		
Atelectasis	4	0
Emphysema	2	0
Idiopathic pulmonary fibrosis	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Interstitial lung disease	14	0
Lung consolidation	4	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	35	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	11	0
Pharyngeal paraesthesia	30	0
Pharyngeal swelling	238	0
Pharyngeal ulceration	14	0
Tonsillar disorder	1	0
Tonsillar erythema	5	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	58	0
Tonsillar inflammation	4	0
Tonsillar ulcer	2	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pleural infections and inflammations</i>		
Lupus pleurisy	2	0
Pleurisy	41	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	25	0
Pneumothorax	7	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	1
<i>Pulmonary oedemas</i>		
Acute lung injury	1	0
Acute pulmonary oedema	3	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	14	0
Pulmonary oedema	21	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	1185	84
Pulmonary infarction	11	1
Pulmonary thrombosis	19	2
Pulmonary venous thrombosis	2	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
Respiratory failure	18	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	9	0
Diaphragmalgia	13	0
Nasal flaring	1	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Painful respiration	6	0
Respiratory symptom	16	0
Suffocation feeling	4	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	9	2
Chronic respiratory disease	2	1
Lung disorder	7	0
Pulmonary mass	3	0
Respiratory disorder	6	0
Respiratory tract congestion	7	0
Respiratory tract haemorrhage	1	0
Respiratory tract irritation	8	0
Respiratory tract oedema	1	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal fistula	1	0
Tracheal pain	3	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	82	0
Catarrh	54	0
Choking	17	0
Choking sensation	8	0
Dry throat	234	0
Dysphonia	120	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	18	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	102	0
Oropharyngeal blistering	23	0
Oropharyngeal discomfort	31	0
Oropharyngeal pain	3753	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	60	0
Rhinalgia	32	0
Rhinorrhoea	1499	0
Sinus pain	535	0
Sneezing	421	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	180	0
Throat lesion	1	0
Throat tightness	181	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	24	0
Yawning	61	0
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	23439	109

Case Series Drug Analysis Print

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

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	80	0
Acne cystic	4	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	226	0
Alopecia areata	17	0
Alopecia totalis	1	0
Alopecia universalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	3	0
Madarosis	2	0
<i>Angioedemas</i>		
Angioedema	294	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1565	0
Hyperhidrosis	8418	0
Hypohidrosis	3	0
Miliaria	183	0
Night sweats	1712	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	423	0
Blister rupture	7	0
Blood blister	76	0
Dermatitis bullous	12	0
Dermatitis herpetiformis	2	0
Erythema multiforme	33	0
Linear IgA disease	1	0
Oedema blister	1	0
Pemphigoid	18	0
Pemphigus	1	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	3	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	1	0
Dry skin	373	0
Macule	9	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	850	0
Papule	91	0
Peau d'orange	3	0
Scab	22	0

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Scar pain	11	0
Sensitive skin	538	0
Skin burning sensation	501	0
Skin discolouration	143	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	38	0
Skin necrosis	5	0
Skin odour abnormal	45	0
Skin plaque	3	0
Skin reaction	226	0
Skin sensitisation	83	0
Skin swelling	81	0
Skin texture abnormal	1	0
Skin tightness	29	0
Skin warm	529	0
Skin weeping	5	0
Sticky skin	7	0
Target skin lesion	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	25	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	156	0
Dermatitis allergic	262	0
Dermatitis atopic	19	0
Dermatitis contact	17	0
Dermatitis diaper	2	0
Dyshidrotic eczema	7	0
Eczema	221	0
Eczema asteatotic	13	0
Eczema nummular	3	0
Eczema weeping	2	0
Hand dermatitis	5	0
Intertrigo	2	0
Perioral dermatitis	4	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	7	0
Skin irritation	116	0
Stasis dermatitis	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	30	0
Drug reaction with eosinophilia and systemic symptoms	13	0
Fixed eruption	4	0
Palmar-plantar erythrodysesthesia syndrome	2	0
<i>Erythemas</i>		
Erythema	3024	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Erythema ab igne	1	0
Palmar erythema	5	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	13	0
Skin exfoliation	114	0
Granulomatous and deep cutaneous inflammatory conditions		
Granuloma annulare	3	0
Hyperkeratoses		
Hyperkeratosis	1	0
Hyperpigmentation disorders		
Melanoderma	2	0
Skin hyperpigmentation	6	0
Solar lentigo	5	0
Hypertrichoses		
Hypertrichosis	1	0
Hypopigmentation disorders		
Skin depigmentation	7	0
Skin hypopigmentation	1	0
Vitiligo	13	0
Lipodystrophies		
Lipoatrophy	2	0
Lipohypertrophy	2	0
Nail and nail bed conditions (excl infections and infestations)		
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	8	0
Onycholysis	1	0
Onychomadesis	1	0
Splinter haemorrhages	2	0
Panniculitides		
Erythema nodosum	25	0
Panniculitis	3	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	20	0
Lichen sclerosus	3	0
Parapsoriasis	1	0
Pityriasis rosea	39	0
Pityriasis rubra pilaris	2	0
Photosensitivity and photodermatosis conditions		
Photodermatosis	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Photosensitivity reaction	136	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
Pigmentation changes NEC		
Pigmentation disorder	11	0
Pilar disorders NEC		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	5	0
Hair texture abnormal	6	0
Piloerection	88	0
Pseudofolliculitis	1	0
Trichodynia	6	0
Trichorrhexis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	6998	0
Pruritus allergic	1	0
Senile pruritus	1	0
Psoriatic conditions		
Guttate psoriasis	22	0
Psoriasis	153	0
Pustular psoriasis	1	0
Purpura and related conditions		
Ecchymosis	5	0
Henoch-Schonlein purpura	11	0
Petechiae	261	0
Purpura	97	0
Pustular conditions		
Acute generalised exanthematous pustulosis	1	0
Rash follicular	4	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	8	0
Rash	7492	0
Rash erythematous	1985	0
Rash macular	645	0
Rash maculo-papular	57	0
Rash morbilliform	40	0
Rash papular	467	0
Rash pruritic	1635	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	68	0
Systemic lupus erythematosus rash	8	0
Rosaceas		
Erythematotelangiectatic rosacea	1	0
Rosacea	34	0
Scaly conditions		
Pityriasis	7	0
Sebaceous gland disorders		
Seborrhoea	7	0
Skin and subcutaneous conditions NEC		
Adiposis dolorosa	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Cutaneous symptom	7	0
Eosinophilic cellulitis	1	0
Skin mass	30	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Diabetic foot	2	0
Diabetic ulcer	1	0
Mucocutaneous ulceration	2	0
Pyoderma gangrenosum	2	0
Skin erosion	40	0
Skin ulcer	25	0
<i>Skin cysts and polyps</i>		
Dermal cyst	14	0
<i>Skin dystrophies</i>		
Skin wrinkling	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	31	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	7	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	8	0
Hypersensitivity vasculitis	3	0
Vasculitic rash	23	1
<i>Skin vasomotor conditions</i>		
Livedo reticularis	48	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	3	0
Telangiectasia	3	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	2	0
Cold urticaria	3	0
Idiopathic urticaria	7	0
Mechanical urticaria	2	0
Solar urticaria	1	0
Urticaria	2085	0
Urticaria chronic	24	0
Urticaria contact	2	0
Urticaria papular	2	0
Urticaria thermal	5	0
Urticarial vasculitis	6	0
Skin disorders SOC TOTAL	43758	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	2	0
Menopause	20	0
Postmenopause	5	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	69	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	3	0
Impaired driving ability	4	0
Impaired work ability	17	0
Loss of personal independence in daily activities	4	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	6	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
Impaired quality of life	1	0

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Reaction Name	Total	Fatal
Social circumstances <small>Social circumstances cont'd</small>		
Refusal of vaccination	1	0
Tattoo	1	0
<i>Tobacco use</i>		
Non-tobacco user	3	0
Tobacco user	2	0
Social circumstances SOC TOTAL	237	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	2	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		
<i>Surgical & medical procedures cont'd</i>		
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	27	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	2	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	2	0
Haemofiltration	1	0
Thrombosis prophylaxis	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	3	0
Hormone therapy	2	0
<i>Immunisations</i>		
COVID-19 immunisation	181	1
Immunisation	80	0
Tuberculosis immunisation	1	0
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Joint therapeutic procedures</i>		
Hip surgery	1	0
Joint injection	2	0
Joint stabilisation	1	0
Knee operation	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	5	0
<i>Limb therapeutic procedures</i>		
Foot amputation	1	0
Leg amputation	2	0
Limb immobilisation	24	0
Limb operation	8	0
Limb reattachment surgery	1	0
Toe amputation	4	0
<i>Mastectomies</i>		
Breast conserving surgery	2	0
<i>Muscle therapeutic procedures</i>		
Muscle relaxant therapy	2	0
<i>Nasal therapeutic procedures</i>		
Nasal irrigation	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Central nervous system stimulation	3	0
<i>Orbit and globe therapeutic procedures</i>		
Eye muscle operation	1	0
<i>Patient positioning</i>		
Prone position	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	3	0
Reproductive system disorder prophylaxis	1	0
<i>Psychiatric therapies</i>		
Antidepressant therapy	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</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	19	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	2	0
Localised alternating hot and cold therapy	5	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	1	0
Physical fitness training	2	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	1	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	561	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	10	0
Hypertensive emergency	2	0
Hypertensive urgency	2	0
Malignant hypertension	2	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	4	0
Giant cell arteritis	45	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	18	0
Labile blood pressure	2	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	2	0
Hypovolaemic shock	1	0
Neurogenic shock	10	0
Peripheral circulatory failure	3	0
Shock	48	1
Shock symptom	5	0
<i>Haemorrhages NEC</i>		
Bloody discharge	10	0
Haematoma	83	0
Haemorrhage	668	2
Internal haemorrhage	21	0
Venous haemorrhage	7	0
<i>Lymphangiopathies</i>		
Lymphorrhoea	1	0
<i>Lymphoedemas</i>		
Lymphoedema	53	0
<i>Non-site specific embolism and thrombosis</i>		

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Arterial thrombosis	22	1
Atheroembolism	1	0
Embolism	244	3
Embolism arterial	3	0
Embolism venous	12	1
Microembolism	3	0
Paradoxical embolism	1	0
Thrombophlebitis migrans	1	0
Thrombosis	1191	23
Venous thrombosis	28	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	8	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	2	0
Hyperaemia	2	0
Neovascularisation	1	0
Superficial vein prominence	4	0
Vascular pain	97	0
Vascular rupture	1	0
Vascular wall discolouration	1	0
Vasodilatation	86	0
Vein collapse	1	0
Vein discolouration	5	0
Vein disorder	14	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	32	0
Deep vein thrombosis	880	7
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	19	0
Pelvic venous thrombosis	14	1
Peripheral artery thrombosis	15	0
Peripheral embolism	9	0
Peripheral vein thrombus extension	1	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	1	0
Thrombophlebitis	97	0

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

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

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Thrombophlebitis superficial	48	0
Venous thrombosis limb	2	0
Peripheral vascular disorders NEC		
Cyanosis	96	0
Erythromelalgia	5	0
Flushing	654	0
Hot flush	1879	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	2	0
Ischaemic limb pain	4	0
Jugular vein occlusion	1	0
Peripheral arterial occlusive disease	3	0
Peripheral artery occlusion	7	0
Peripheral coldness	1175	0
Peripheral ischaemia	31	2
Poor peripheral circulation	44	0
Raynaud's phenomenon	119	0
Phlebitis NEC		
Phlebitis	47	0
Phlebitis superficial	9	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific vascular disorders NEC		
Pallor	377	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	1	0
Spider vein	11	0
Varicophlebitis	4	0
Varicose vein	103	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	5	0
Hypertension	729	0
Labile hypertension	1	0
Systolic hypertension	2	0
Venous hypertension	3	0
White coat hypertension	10	0
Vascular hypotensive disorders		
Capillary leak syndrome	8	0
Hypotension	461	0
Orthostatic hypotension	41	0
Vascular malformations and acquired anomalies		
Arteriovenous fistula	1	0
Vasculitides NEC		
Behcet's syndrome	1	0
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	108	3
Vena caval embolism and thrombosis		

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 03-Jun-2021

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vena cava thrombosis	3	1
Vascular disorders SOC TOTAL	10045	54
TOTAL REACTIONS FOR DRUG	717250	863
TOTAL REPORTS	195641	
TOTAL FATAL OUTCOME REPORTS		863