

COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Data Lock Date: 19-May-2021 18:30:09

All UK spontaneous reports received between 4/01/21 and 19/05/2021 for COVID-19 vaccine Oxford University/AstraZeneca.

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

Case Series Drug Analysis Print

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Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	6	0
Iron deficiency anaemia	5	0
Pernicious anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	63	0
Blood loss anaemia	2	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	6	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	3	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	78	0
Spontaneous haematoma	5	0
Spontaneous haemorrhage	1	0
<i>Coagulation factor deficiencies</i>		
Hypofibrinogenaemia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	6	0
Antiphospholipid syndrome	19	0
Coagulopathy	39	0
Disseminated intravascular coagulation	15	1
Hypercoagulation	17	1
<i>Eosinophilic disorders</i>		
Eosinophilia	16	0
Hypereosinophilic syndrome	1	0
<i>Haematological disorders</i>		
Blood disorder	5	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	5	0
<i>Leukocytoses NEC</i>		
Leukocytosis	3	0
Lymphocytosis	5	0
Monocytosis	2	0
Neutrophilia	12	0
<i>Leukopenias NEC</i>		
Leukopenia	8	0
Lymphopenia	8	0
<i>Lymphatic system disorders NEC</i>		
Lymph node fibrosis	1	0
Lymph node pain	464	0
Lymphadenitis	24	0
Lymphadenopathy	4001	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Lymphatic disorder	1	0
Pseudolymphoma	3	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Myelosuppression	3	0
Pancytopenia	13	0
<i>Neutropenias</i>		
Agranulocytosis	4	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	68	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	3	0
Platelet disorder	4	0
<i>Polycythaemia (excl rubra vera)</i>		
Stress polycythaemia	2	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	4	0
<i>Red blood cell abnormal findings NEC</i>		
Anisocytosis	1	0
Macrocytosis	1	0
Poikilocytosis	1	0
Polychromasia	2	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 infarction	10	0
Splenic thrombosis	1	0
Splenic varices	1	0
Splenic vein thrombosis	9	0
Splenomegaly	5	0
<i>Thrombocytopenias</i>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	10	0
Immune thrombocytopenia	172	1
Thrombocytopenia	631	5
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	1	0
<i>Thrombocytoses</i>		
Thrombocytosis	7	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	3	0
Blood disorders SOC TOTAL	5820	8

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	1	0
Aortic valve stenosis	1	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	14	0
Atrioventricular block complete	3	0
Atrioventricular block second degree	3	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	3	1
Atrial thrombosis	2	0
Cardiac disorder	42	0
Cardiac dysfunction	1	0
Cardiac ventricular thrombosis	6	2
Cardiovascular disorder	6	0
Cardiovascular insufficiency	10	0
Intracardiac thrombus	3	0
<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	4106	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	1
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	8	0
Congestive cardiomyopathy	7	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
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	45	6
Cardiac failure acute	5	0
Cardiac failure congestive	2	1
Cardiogenic shock	5	2
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	5	0
Acute myocardial infarction	44	7

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Cardiac disorders Cardiac disorders cont'd		
Angina pectoris	142	0
Angina unstable	13	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	2	0
Myocardial infarction	246	35
Myocardial ischaemia	19	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	4	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiomegaly	9	0
Left atrial dilatation	1	0
Left ventricular dilatation	1	0
Left ventricular dysfunction	11	0
Left ventricular hypertrophy	1	0
Myocardial rupture	1	0
Right ventricular dysfunction	2	0
Ventricular hypertrophy	3	1
Noninfectious myocarditis		
Myocarditis	26	1
Noninfectious pericarditis		
Pericarditis	47	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	14	0
Pericardial haemorrhage	4	2
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	91	0
Bradycardia	55	0
Cardiac fibrillation	2	0
Cardiac flutter	154	0
Extrasystoles	92	0
Heart alternation	3	0
Paroxysmal arrhythmia	2	0
Postural orthostatic tachycardia syndrome	9	0
Tachyarrhythmia	10	0
Tachycardia	1099	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	2	1
Supraventricular arrhythmias		
Arrhythmia supraventricular	13	0
Atrial fibrillation	220	0
Atrial flutter	25	0
Atrial tachycardia	1	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	2	0

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Cardiac disorders Cardiac disorders cont'd		
Sinus node dysfunction	1	0
Sinus tachycardia	59	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	24	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	3	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	129	30
Cardio-respiratory arrest	2	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	5	0
Ventricular fibrillation	5	0
Ventricular tachycardia	12	0
Cardiac disorders SOC TOTAL	6959	105

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Arterial disorders congenital</i>		
Congenital arterial malformation	1	0
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 21	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	10	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	5	0
Ventricular septal defect	1	0
<i>Cardiovascular disorders congenital NEC</i>		
Congenital cardiovascular anomaly	1	0
<i>Central nervous system disorders congenital NEC</i>		
Encephalocele	3	0
Neural tube defect	1	1
Syringomyelia	2	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	3	0
<i>Cerebral disorders congenital</i>		
Anencephaly	1	0
Cerebral palsy	6	0
<i>Coagulation disorders congenital</i>		
Haemophilia	2	0
Protein C deficiency	3	0
Protein S deficiency	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	3	0
Young's syndrome	3	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	6	0
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	3	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	1	0
Porphyria acute	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	1	0
<i>Lysosomal storage disorders</i>		
Mucopolysaccharidosis	1	0
<i>Male reproductive tract disorders congenital</i>		
Hydrocele	1	0
Micropenis	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital hand malformation	1	0
Limb reduction defect	1	0
Polydactyly	1	0

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Congenital disorders Congenital disorders cont'd		
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	2	0
Otopalatodigital spectrum disorder	1	0
<i>Neurological disorders congenital NEC</i>		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	1	0
<i>Non-site specific muscle disorders congenital</i>		
Muscular dystrophy	2	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	1	0
<i>Pancreatic disorders congenital</i>		
Hereditary pancreatitis	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Paroxysmal extreme pain disorder	11	0
<i>Pulmonary and bronchial disorders congenital</i>		
Cystic fibrosis	4	0
<i>Renal disorders congenital</i>		
Congenital cystic kidney disease	1	0
<i>Sex chromosomal abnormalities</i>		
Klinefelter's syndrome	1	0
<i>Vascular anomalies congenital NEC</i>		
Arteriovenous malformation	1	0
Klippel-Trenaunay syndrome	2	0
Congenital disorders SOC TOTAL	103	1

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Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	22	0
Ear discomfort	78	0
Ear disorder	9	0
Ear haemorrhage	10	0
Ear pain	1657	0
Ear pruritus	4	0
Ear swelling	54	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	4	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	25	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	4	0
<i>Hearing losses</i>		
Deafness	237	0
Deafness bilateral	8	0
Deafness neurosensory	15	0
Deafness transitory	3	0
Deafness unilateral	33	0
Hypoacusis	145	0
Sudden hearing loss	43	0
<i>Hyperacusia</i>		
Hyperacusis	98	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	5	0
Meniere's disease	18	0
Vestibular disorder	5	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	91	0
Phobic postural vertigo	1	0
Tinnitus	2663	0
Vertigo	1476	0
Vertigo labyrinthine	9	0
Vertigo positional	85	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	6844	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	3	0
Thyroiditis	7	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	28	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	2	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	5	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	7	0
Ovulation delayed	5	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	1	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	3	0
<i>Hypothalamic and pituitary disorders NEC</i>		
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	12	0
Thyroid disorder	7	0
Thyroid mass	2	0
Thyroid pain	10	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	4	0
Hyperthyroidism	23	0
Thyrotoxic crisis	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	36	0
Endocrine disorders SOC TOTAL	210	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	3	0
<i>Cataract conditions</i>		
Cataract	11	0
Cataract cortical	2	0
Cataract subcapsular	2	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	35	0
Vitreous floaters	118	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	96	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	93	0
Excessive eye blinking	6	0
Eyelid ptosis	33	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	5	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	6	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	16	0
Iritis	9	0
Uveitis	27	0
<i>Lacrimation disorders</i>		
Dry eye	232	0
Lacrimation increased	200	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	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	13	0
Chalazion	1	0
Eczema eyelids	2	0
Erythema of eyelid	5	0
Eyelid cyst	10	0

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Eye disorders Eye disorders cont'd		
Eyelid irritation	3	0
Eyelid margin crusting	1	0
Eyelid oedema	10	0
Eyelid rash	10	0
Swelling of eyelid	94	0
Lid, lash and lacrimal structural disorders		
Eyelid exfoliation	2	0
Eyelid skin dryness	3	0
Eyelid thickening	3	0
Growth of eyelashes	5	0
Lagophthalmos	2	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	3	0
Eye haemorrhage	72	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	16	0
Eye oedema	14	0
Eye pain	2861	0
Eye swelling	486	0
Eye symptom	7	0
Eye ulcer	9	0
Eyelid disorder	5	0
Eyelid pain	16	0
Eyelids pruritus	7	0
Ocular discomfort	52	0
Periorbital oedema	15	0
Periorbital pain	3	0
Periorbital swelling	79	0
Retinal disorder	1	0
Ocular infections, inflammations and associated manifestations		
Autoimmune eye disorder	1	0
Eye allergy	21	0
Eye discharge	20	0
Eye inflammation	26	0
Eye irritation	177	0
Eye pruritus	240	0
Limbal swelling	6	0
Ocular hyperaemia	330	0
Ocular rosacea	1	0
Ocular nerve and muscle disorders		
Extraocular muscle paresis	7	0
Eye movement disorder	36	0
Gaze palsy	3	0
Ocular myasthenia	2	0
Ophthalmoplegia	1	0
Strabismus	3	0
Ocular sensation disorders		
Abnormal sensation in eye	21	0

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Eye disorders Eye disorders cont'd		
Asthenopia	295	0
Eye paraesthesia	3	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	33	0
Hypoaesthesia eye	22	0
Photophobia	864	0
<i>Optic disc abnormalities NEC</i>		
Optic atrophy	1	0
Optic discs blurred	1	0
Papilloedema	8	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	5	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	3	0
<i>Pupil disorders</i>		
Miosis	10	0
Mydriasis	25	0
Pupil fixed	9	0
Pupils unequal	8	0
<i>Refractive and accommodative disorders</i>		
Altered visual depth perception	4	0
Hypermetropia	1	0
Refraction disorder	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal aneurysm	1	0
Retinal artery embolism	2	0
Retinal artery occlusion	13	0
Retinal haemorrhage	10	0
Retinal infarction	1	0
Retinal vascular occlusion	1	0
Retinal vascular thrombosis	2	0
Retinal vein occlusion	37	0
Retinal vein thrombosis	5	0
Retinal vein varices	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular cyst	1	0
Macular degeneration	5	0
Macular detachment	1	0
Macular hole	2	0
Neovascular age-related macular degeneration	8	0
Retinal detachment	17	0
Retinal drusen	1	0
Retinal tear	9	0
Retinal toxicity	2	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	13	0
Retinopathy	6	0

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Eye disorders Eye disorders cont'd		
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	12	0
Scleritis	5	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	2	0
Exophthalmos	4	0
<i>Visual colour distortions</i>		
Chloropsia	1	0
Chromatopsia	1	0
Cyanopsia	1	0
Erythropsia	3	0
Xanthopsia	6	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0
Diplopia	237	0
Dysmetropsia	1	0
Halo vision	10	0
Metamorphopsia	26	0
Photopsia	246	0
Scintillating scotoma	5	0
Vision blurred	2067	0
Visual brightness	7	0
Visual snow syndrome	3	0
<i>Visual field disorders</i>		
Visual field defect	21	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	6	0
Blindness	192	0
Blindness transient	16	0
Blindness unilateral	18	0
Central vision loss	2	0
Night blindness	4	0
Sudden visual loss	3	0
Visual acuity reduced	24	0
Visual acuity reduced transiently	1	0
Visual impairment	505	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Optic neuropathy	4	0
Eye disorders SOC TOTAL	10530	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	3	0
Gastrointestinal sounds abnormal	16	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	27	1
Pancreatitis acute	12	0
Pancreatitis chronic	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
<i>Anal and rectal pains</i>		
Proctalgia	24	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	4	0
Anorectal swelling	1	0
Rectal discharge	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	12	0
Tongue cyst	4	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	36	0
Colitis ischaemic	4	1
Colitis microscopic	3	0
Colitis ulcerative	64	0
Crohn's disease	61	0
Inflammatory bowel disease	8	0
Terminal ileitis	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
<i>Dental disorders NEC</i>		
Diastema	1	0
Loose tooth	1	0
Malpositioned teeth	1	0
Teething	18	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	11	0
Dental paraesthesia	16	0
Hyperaesthesia teeth	43	0
Hypoaesthesia teeth	2	0
Toothache	261	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Dental surface disorders</i>		

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Tooth discolouration	13	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	10	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	7427	0
Diarrhoea haemorrhagic	26	0
<i>Diverticula</i>		
Diverticulum	7	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	691	0
Epigastric discomfort	16	0
Eructation	77	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	14	0
Faecaloma	2	0
Faeces discoloured	39	0
Faeces hard	4	0
Faeces pale	6	0
Faeces soft	18	0
Mucous stools	11	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	388	0
Flatulence	339	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	7	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	9	0
Gastric ulcer haemorrhage	1	0
Gastric ulcer perforation	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	3	0
Gastritis	64	0
Reflux gastritis	13	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	3	0
Abdominal pain	3736	0
Abdominal pain lower	187	0
Abdominal pain upper	4270	0
Abdominal rigidity	46	0
Abdominal tenderness	17	0
Gastrointestinal pain	264	0
Oesophageal pain	6	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	349	0
Duodenogastric reflux	2	0
Gastric dilatation	14	0
Gastrooesophageal reflux disease	163	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Impaired gastric emptying	4	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
<i>Gastrointestinal disorders NEC</i>		
Appendix disorder	1	0
Food poisoning	10	0
Functional gastrointestinal disorder	10	0
Gastric disorder	8	0
Gastrointestinal disorder	20	0
Gastrointestinal oedema	3	0
Gastroptosis	1	0
Neurogenic bowel	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	4	0
Change of bowel habit	12	0
Defaecation disorder	1	0
Dyschezia	12	0
Gastrointestinal motility disorder	2	0
Oesophageal achalasia	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Appendicitis noninfective	1	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	2	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1338	0
Abdominal symptom	5	0
Acute abdomen	13	0
Anal incontinence	32	0
Breath odour	18	0
Dysphagia	181	0
Intestinal congestion	1	0
Odynophagia	25	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	2	1
Defaecation urgency	12	0
Frequent bowel movements	37	0
Irritable bowel syndrome	90	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>		
Gastrointestinal perforation	1	0
<i>Gastrointestinal vascular malformations</i>		

Case Series Drug Analysis Print

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Report Run Date: 20-May-2021
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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastric antral vascular ectasia	6	0
Gastrointestinal vascular occlusion and infarction		
Intestinal infarction	3	0
Intestinal ischaemia	21	1
Mesenteric artery embolism	1	0
Mesenteric artery thrombosis	2	0
Mesenteric vein thrombosis	13	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	3	0
Visceral venous thrombosis	9	1
Gingival disorders, signs and symptoms NEC		
Epulis	1	0
Gingival blister	18	0
Gingival discomfort	5	0
Gingival disorder	12	0
Gingival hypertrophy	2	0
Gingival oedema	2	0
Gingival pain	187	0
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	40	0
Gingival ulceration	7	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	19	0
Gingival haemorrhages		
Gingival bleeding	104	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	42	0
Haemorrhoids thrombosed	7	0
Inguinal hernias		
Inguinal hernia	3	0
Intestinal haemorrhages		
Anal haemorrhage	25	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	0
Mesenteric haemorrhage	2	0
Rectal haemorrhage	80	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	14	0
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Acetonaemic vomiting	1	0
Discoloured vomit	17	0
Faecal vomiting	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Infantile vomiting	2	0
Nausea	29649	0
Regurgitation	2	0
Retching	208	0
Vomiting	9900	3
Vomiting projectile	134	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	20	0
Haematemesis	65	0
Haematochezia	67	0
Melaena	6	0
Upper gastrointestinal haemorrhage	2	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	10	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	4	0
Dry mouth	1000	0
Lip dry	72	0
Saliva altered	5	0
Saliva discolouration	1	0
Salivary hypersecretion	67	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	18	0
Cheilitis	31	0
Chronic cheek biting	1	0
Enlarged uvula	7	0
Leukoplakia oral	2	0
Lip blister	26	0
Lip disorder	3	0
Oral disorder	11	0
Oral lichen planus	8	0
Oral papule	2	0
Palatal disorder	2	0
Uvulitis	5	0
<i>Oral soft tissue haemorrhages</i>		
Lip haemorrhage	3	0
Mouth haemorrhage	28	0
Oral blood blister	42	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	10	0
Coating in mouth	3	0
Hypoaesthesia oral	506	0
Lip discolouration	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Lip erythema	4	0
Lip exfoliation	9	0
Lip pain	49	0
Lip pruritus	15	0
Oral discharge	1	0
Oral discomfort	72	0
Oral mucosal blistering	26	0
Oral mucosal eruption	19	0
Oral mucosal erythema	4	0
Oral mucosal exfoliation	8	0
Oral mucosal roughening	3	0
Oral pain	293	0
Oral pruritus	19	0
Paraesthesia oral	694	0
Oral soft tissue swelling and oedema		
Lip oedema	8	0
Lip swelling	790	0
Mouth swelling	101	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	12	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peritoneal and retroperitoneal disorders		
Ascites	5	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	0
Rectal inflammations NEC		
Proctitis	3	0
Salivary gland disorders NEC		
Salivary gland calculus	3	0
Salivary gland pain	11	0
Salivary gland enlargements		
Parotid gland enlargement	9	0
Salivary gland enlargement	4	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Aphthous ulcer	54	0
Lip ulceration	14	0
Mouth ulceration	614	0
Stomatitis	84	0
Tongue disorders		
Glossitis	14	0
Plicated tongue	4	0
Tongue disorder	26	0
Tongue geographic	2	0
Tongue haemorrhage	2	0
Tongue ulceration	24	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	220	0
Scalloped tongue	3	0
Stiff tongue	3	0
Strawberry tongue	1	0
Swollen tongue	493	0
Tongue blistering	23	0
Tongue coated	31	0
Tongue discolouration	25	0
Tongue discomfort	39	0
Tongue dry	18	0
Tongue eruption	6	0
Tongue erythema	5	0
Tongue exfoliation	1	0
Tongue movement disturbance	6	0
Tongue oedema	15	0
Tongue pruritus	3	0
Tongue rough	2	0
Tongue spasm	3	0
<i>Tooth missing</i>		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	67335	11

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	13	0
Administration site coldness	1	0
Administration site erythema	6	0
Administration site extravasation	2	0
Administration site induration	1	0
Administration site mass	1	0
Administration site pain	36	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	49	0
Puncture site haemorrhage	1	0
Puncture site pain	21	0
Puncture site reaction	3	0
Puncture site swelling	1	0
<i>Adverse effect absent</i>		
No adverse event	21	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site bruise	22	0
Application site burn	3	0
Application site coldness	1	0
Application site discharge	1	0
Application site discolouration	1	0
Application site erythema	25	0
Application site exfoliation	1	0
Application site haemorrhage	1	0
Application site hypersensitivity	1	0
Application site inflammation	1	0
Application site joint pain	1	0
Application site pain	40	0
Application site pruritus	16	0
Application site rash	2	0
Application site scar	1	0
Application site swelling	4	0
Application site vesicles	7	0
Application site warmth	1	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	3975	3
Chronic fatigue syndrome	99	0
Decreased activity	6	0
Fatigue	42407	0
Malaise	10627	3
Sluggishness	21	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Body temperature altered</i>		
Hyperthermia	9	0
Hypothermia	47	0
Temperature regulation disorder	22	0
<i>Complications associated with device NEC</i>		
Complication of device removal	1	0
Injury associated with device	3	0
Medical device site joint pain	1	0
Phantom shocks	4	0
<i>Death and sudden death</i>		
Brain death	4	3
Death	244	238
Drowning	1	0
Sudden death	27	27
<i>Febrile disorders</i>		
Hyperpyrexia	40	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	50108	0
<i>Feelings and sensations NEC</i>		
Chills	39855	0
Early satiety	1	0
Feeling abnormal	2485	0
Feeling cold	4725	0
Feeling drunk	108	0
Feeling hot	2055	0
Feeling jittery	38	0
Feeling of body temperature change	856	0
Feeling of relaxation	1	0
Hangover	156	0
Hunger	67	0
Sensation of blood flow	10	0
Sensation of foreign body	37	0
Temperature intolerance	63	0
Thirst	1129	0
Thirst decreased	9	0
<i>Fibrosis NEC</i>		
Fibrosis	3	0
<i>Gait disturbances</i>		
Decreased gait velocity	2	0
Gait disturbance	296	0
Gait inability	153	0
Loss of control of legs	38	0
<i>General signs and symptoms NEC</i>		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	178	0
Crepitations	5	0
Crying	228	0
Developmental delay	4	0
Discharge	6	0
Disease progression	1	0
Disease recurrence	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Effusion	1	0
Energy increased	20	0
Exercise tolerance decreased	23	0
Foaming at mouth	4	0
General physical health deterioration	18	1
General symptom	10	0
Glassy eyes	5	0
High-pitched crying	4	0
Ill-defined disorder	3	0
Illness	4316	0
Induration	18	0
Influenza like illness	8517	1
Irritability postvaccinal	2	0
Local reaction	149	0
Moaning	8	0
Multiple organ dysfunction syndrome	13	4
Nonspecific reaction	3	0
Organ failure	1	0
Perforation	1	0
Peripheral swelling	4766	0
Pre-existing condition improved	11	0
Premature ageing	1	0
Prolapse	1	0
Screaming	21	0
Secretion discharge	22	0
Sensitivity to weather change	1	0
Stenosis	1	0
Swelling	2219	0
Swelling face	826	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 warmth	7	0
Inflammations		
Granuloma	1	0
Inflammation	550	0
Systemic inflammatory response syndrome	3	0
Infusion site reactions		
Infusion site bruising	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site erythema	2	0
Infusion site mass	2	0
Infusion site nodule	2	0
Infusion site pain	10	0
Infusion site urticaria	1	0
Infusion site warmth	6	0
Injection site reactions		
Injected limb mobility decreased	32	0
Injection site atrophy	8	0
Injection site bruising	100	0
Injection site coldness	5	0
Injection site cyst	2	0
Injection site discolouration	4	0
Injection site discomfort	15	0
Injection site dryness	1	0
Injection site erythema	526	0
Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site haematoma	2	0
Injection site haemorrhage	10	0
Injection site hypersensitivity	4	0
Injection site hypoaesthesia	12	0
Injection site indentation	11	0
Injection site induration	7	0
Injection site inflammation	55	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 mass	1269	0
Injection site movement impairment	3	0
Injection site muscle weakness	1	0
Injection site necrosis	1	0
Injection site nodule	4	0
Injection site oedema	24	0
Injection site pain	4033	0
Injection site papule	2	0
Injection site paraesthesia	21	0
Injection site pruritus	262	0
Injection site rash	269	0
Injection site reaction	112	0
Injection site scab	4	0
Injection site scar	5	0
Injection site swelling	207	0
Injection site ulcer	1	0
Injection site urticaria	35	0
Injection site vesicles	10	0
Injection site warmth	323	0
Interactions		
Drug interaction	25	0
Inhibitory drug interaction	8	0
Mass conditions NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Cyst	16	0
Mass	62	0
Nodule	14	0
<i>Mucosal findings abnormal</i>		
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	2	0
Polyp	2	0
<i>Necrosis NEC</i>		
Fat necrosis	2	0
Necrosis	7	0
<i>Oedema NEC</i>		
Face oedema	28	0
Localised oedema	10	0
Oedema	53	0
Oedema peripheral	100	0
<i>Pain and discomfort NEC</i>		
Axillary pain	611	0
Chest discomfort	1661	0
Chest pain	3994	0
Discomfort	430	0
Facial discomfort	14	0
Facial pain	216	0
Hernia pain	2	0
Inflammatory pain	18	0
Non-cardiac chest pain	33	0
Pain	13899	0
Suprapubic pain	1	0
Tenderness	1692	0
Visceral pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	167	1
Adverse event	16	0
Adverse reaction	39	0
Diet failure	1	0
Drug ineffective	114	0
Drug intolerance	3	0
Immediate post-injection reaction	4	0
Inadequate analgesia	20	0
No reaction on previous exposure to drug	47	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 ineffective	5	0
Therapeutic reaction time decreased	1	0
Therapeutic response decreased	1	0
Therapeutic response shortened	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Therapeutic response unexpected	89	0
Therapy non-responder	3	0
Treatment failure	5	0
Vaccination failure	22	0
Vaccine positive rechallenge	1	0
Trophic disorders		
Atrophy	3	0
Calcinosis	1	0
Dysplasia	2	0
Ulcers NEC		
Ulcer	35	0
Ulcer haemorrhage	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	17	0
Shoulder injury related to vaccine administration	31	0
Vaccination site atrophy	1	0
Vaccination site bruising	114	0
Vaccination site coldness	1	0
Vaccination site cyst	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	10	0
Vaccination site discomfort	39	0
Vaccination site dryness	1	0
Vaccination site erythema	612	0
Vaccination site extravasation	1	0
Vaccination site granuloma	8	0
Vaccination site haemorrhage	5	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	3	0
Vaccination site hypoaesthesia	22	0
Vaccination site induration	61	0
Vaccination site inflammation	46	0
Vaccination site injury	3	0
Vaccination site irritation	12	0
Vaccination site joint discomfort	1	0
Vaccination site joint erythema	4	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	8	0
Vaccination site joint pain	41	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	467	0
Vaccination site movement impairment	57	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	1750	0
Vaccination site papule	3	0
Vaccination site paraesthesia	12	0
Vaccination site pruritus	98	0
Vaccination site rash	160	0
Vaccination site reaction	19	0
Vaccination site scab	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021

Data Lock Date: 19-May-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site scar	4	0
Vaccination site swelling	433	0
Vaccination site urticaria	10	0
Vaccination site vesicles	7	0
Vaccination site warmth	335	0
<i>Vascular complications associated with device</i>		
Vascular stent occlusion	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	6	0
Withdrawal syndrome	72	0
General disorders SOC TOTAL	217510	281

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	22	0
Cholangitis	3	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	10	0
Cholelithiasis	10	0
<i>Cholestasis and jaundice</i>		
Cholestasis	4	0
Jaundice	41	0
Jaundice cholestatic	7	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	10	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	1	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	1	0
Hepatic vein thrombosis	10	0
Portal hypertension	1	0
Portal vein phlebitis	1	0
Portal vein thrombosis	48	4
Portosplenomesenteric venous thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	51	0
Hepatomegaly	3	0
Liver tenderness	4	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic necrosis	1	0
Hepatic steatosis	4	0
Hepatitis	20	0
Hepatitis acute	5	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	2	0
Hepatic disorders SOC TOTAL	311	7

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	21	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	1113	0
Infusion related hypersensitivity reaction	4	0
Mite allergy	2	0
Multiple allergies	12	0
Serum sickness	15	0
Serum sickness-like reaction	13	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	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	43	0
Contrast media reaction	3	0
Drug hypersensitivity	57	0
Food allergy	17	0
Oral allergy syndrome	1	0
Reaction to colouring	1	0
Reaction to excipient	13	0
Reaction to preservatives	13	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	555	2
Anaphylactic shock	97	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	3	0
<i>Atopic disorders</i>		
Atopy	2	0
Seasonal allergy	64	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	25	0
<i>Endocrine autoimmune disorders</i>		
Hashitoxicosis	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	25	0
Cytokine release syndrome	1	0
Cytokine storm	2	0
Haemophagocytic lymphohistiocytosis	6	0
Immune system disorder	17	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	1	0
Pre-engraftment immune reaction	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021

Data Lock Date: 19-May-2021 18:30:09

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Sensitisation	26	0
Immunodeficiency disorders NEC		
Immunodeficiency	2	0
Immunosuppression	5	0
Transplant rejections		
Corneal graft rejection	2	0
Transplant rejection	6	0
Vasculitides		
Eosinophilic granulomatosis with polyangiitis	1	0
Immune system disorders SOC TOTAL	2239	2

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
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	24	0
Appendicitis perforated	3	0
Diarrhoea infectious	1	0
Diverticulitis	19	0
Dysentery	4	0
Gastroenteritis	28	0
Gastrointestinal infection	5	0
Large intestine infection	2	0
Peritonitis	2	0
<i>Aspergillus infections</i>		
Aspergillus infection	1	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Arthritis bacterial	4	0
Bacterial infection	22	1
Bacterial vaginosis	1	0
Cellulitis	441	1
Ear infection bacterial	1	0
Endocarditis bacterial	2	0
Folliculitis	9	0
Injection site cellulitis	7	0
Perichondritis	1	0
Periorbital cellulitis	2	0
Pneumonia bacterial	4	1
Post procedural cellulitis	1	0
Skin bacterial infection	4	0
Urinary tract infection bacterial	4	0
Vaccination site cellulitis	20	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	6	0
Relapsing fever	1	0
<i>Breast infections</i>		
Mastitis	24	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

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Balanitis candida	1	0
Candida infection	47	0
Oral candidiasis	35	0
Skin candida	2	0
Vulvovaginal candidiasis	37	0
Cardiac infections		
Endocarditis	1	0
Central nervous system and spinal infections		
Cavernous sinus thrombosis	5	0
Central nervous system infection	1	0
Encephalitis	27	0
Encephalomyelitis	2	0
Extradural abscess	1	0
Meningitis	21	0
Myelitis	10	0
Chlamydial infections		
Chlamydial infection	1	0
Clostridia infections		
Clostridium difficile colitis	2	0
Clostridium difficile infection	2	0
Tetanus	2	0
Coronavirus infections		
Asymptomatic COVID-19	3	0
COVID-19	391	22
COVID-19 pneumonia	23	7
Coronavirus infection	4	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	33	0
Corynebacteria infections		
Diphtheria	2	0
Coxiella infections		
Q fever	102	0
Dental and oral soft tissue infections		
Abscess oral	3	0
Gingival abscess	5	0
Gingivitis	22	0
Lip infection	1	0
Oral infection	1	0
Oral pustule	2	0
Parotitis	10	0
Pericoronitis	2	0
Periodontitis	1	0
Sialoadenitis	1	0
Tongue abscess	3	0
Tooth abscess	12	0
Tooth infection	9	0
Ear infections		
Ear infection	73	0
Labyrinthitis	110	0
Mastoiditis	3	0
Otitis externa	3	0
Otitis media	10	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
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	40	0
<i>Escherichia infections</i>		
Escherichia infection	2	0
Escherichia sepsis	2	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	65	0
Eye infection	20	0
Eyelid boil	2	0
Eyelid infection	3	0
Hordeolum	26	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	13	0
Fungal skin infection	5	0
Oral fungal infection	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	43	0
Genital herpes simplex	1	0
Haemorrhagic varicella syndrome	1	0
Herpes dermatitis	2	0
Herpes ophthalmic	14	0
Herpes simplex	32	0
Herpes simplex reactivation	2	0
Herpes virus infection	12	0
Herpes zoster	997	0
Herpes zoster oticus	9	0
Herpes zoster reactivation	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Meningoencephalitis herpetic	1	0
Nasal herpes	13	0
Ophthalmic herpes simplex	1	0
Ophthalmic herpes zoster	7	0
Oral herpes	584	0
Varicella	28	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	26	0
Abscess limb	16	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Coinfection	1	0
Device related infection	1	0
Genital abscess	1	0
Infected bite	2	0
Infected cyst	1	0
Infection	376	3
Infection in an immunocompromised host	3	0
Infectious thyroiditis	1	0
Injection site abscess	3	0
Injection site infection	15	0
Localised infection	91	0
Lymph gland infection	3	0
Omphalitis	1	0
Pathogen resistance	2	0
Respiratory tract infection	6	0
Toxic shock syndrome	1	0
Vaccination site abscess	3	0
Vaccination site infection	21	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	7	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H2N2 influenza	2	0
Influenza	5990	0
<i>Klebsiella infections</i>		
Pneumonia klebsiella	1	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	2	0
Bronchitis	19	0
Infectious pleural effusion	3	0
Infective exacerbation of bronchiectasis	1	0
Lower respiratory tract infection	196	3
Pneumonia	169	17
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	5	0
Orchitis	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Mumps viral infections</i>		
Mumps	6	0
<i>Muscle and soft tissue infections</i>		
Muscle abscess	1	0
Soft tissue infection	5	0
<i>Orthopox viral infections</i>		
Cow pox	1	0
<i>Paravaccinia infections</i>		
Paravaccinia	1	0
<i>Plasmodia infections</i>		
Malaria	5	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Polyomavirus infections</i>		
Progressive multifocal leukoencephalopathy	1	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	2	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	2	0
HIV-associated neurocognitive disorder	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Salmonella infections</i>		
Typhoid fever	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Abdominal sepsis	1	0
Bacteraemia	1	0
Neutropenic sepsis	7	0
Sepsis	71	8
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	8	0
Septic shock	4	1
Urosepsis	5	1
Viraemia	3	0
<i>Skin structures and soft tissue infections</i>		
Carbuncle	1	0
Dermatitis infected	9	0
Eczema infected	1	0
Impetigo	6	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	14	0
Rash pustular	14	0
Skin infection	59	0
Subcutaneous abscess	7	0
Vaccination site pustule	3	0
<i>Staphylococcal infections</i>		
Furuncle	34	0
Staphylococcal bacteraemia	1	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	3	1
Toxic shock syndrome staphylococcal	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
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	4	0
Trypanosomal infections		
African trypanosomiasis	6	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	3	0
Meningitis tuberculous	1	0
Pulmonary tuberculosis	2	0
Tuberculosis	4	0
Upper respiratory tract infections		
Acute sinusitis	3	0
Chronic sinusitis	12	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	20	0
Nasal vestibulitis	1	0
Nasopharyngitis	1493	0
Pharyngitis	23	0
Rhinitis	41	0
Sinobronchitis	1	0
Sinusitis	265	0
Tonsillitis	62	0
Tracheitis	1	0
Upper respiratory tract infection	5	0
Urinary tract infections		
Cystitis	69	0
Genitourinary tract infection	1	0
Kidney infection	39	0
Pyelonephritis	3	0
Urinary tract infection	164	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

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Ear infection viral	1	0
Encephalitis viral	6	0
Eye infection viral	1	0
Gastritis viral	1	0
Gastroenteritis viral	58	0
Gastrointestinal viral infection	1	0
Hepatitis viral	2	0
Meningitis viral	15	0
Pneumonia viral	6	1
Post viral fatigue syndrome	86	0
Sweating fever	683	0
Vestibular neuronitis	20	0
Viral diarrhoea	4	0
Viral infection	53	0
Viral labyrinthitis	5	0
Viral myocarditis	2	0
Viral pericarditis	1	0
Viral pharyngitis	23	0
Viral rash	64	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	14228	69

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Abdomen crushing	3	0
Colon injury	1	0
Lip injury	2	0
Mouth injury	1	0
Oral contusion	11	0
Palate injury	1	0
Splenic rupture	3	0
Tongue injury	2	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	2	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>		
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	3	0
Vascular injury	3	0
<i>Cerebral injuries NEC</i>		
Brain contusion	10	0
Brain herniation	4	0
Concussion	4	0
Cranio-cerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	1
Subdural haemorrhage	2	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
Chest injury	1	0
Foreign body in throat	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	56	0
Cranial nerve injuries		
Cranial nerve injury	1	0
Optic nerve injury	2	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	6	0
Exposure via breast milk	41	0
Foetal exposure during pregnancy	39	0
Maternal exposure during breast feeding	951	0
Maternal exposure during pregnancy	203	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	4	0
Paternal exposure during pregnancy	16	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	42	0
Eye injury	20	0
Eyelid contusion	1	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 exhaustion	4	0
Heat illness	4	0
Heat oedema	13	0
Heat stroke	7	0
Intentional product misuses		
Intentional product misuse	1	0
Intentional product use issues		
Intentional product use issue	1	0
Limb fractures and dislocations		
Ankle fracture	3	0
Clavicle fracture	12	0
Femoral neck fracture	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	4	0
Device use issue	1	0
Drug titration error	1	0
Inadequate aseptic technique in use of product	1	0
Intercepted medication error	2	0
Medication error	32	0
Product use issue	3	0
Vaccination error	5	0
Wrong drug	4	0
Wrong technique in product usage process	6	0
Muscle, tendon and ligament injuries		
Epicondylitis	11	0
Ligament injury	2	0
Ligament rupture	1	0
Ligament sprain	14	0
Muscle injury	26	0
Muscle rupture	12	0
Muscle strain	34	0
Post-traumatic neck syndrome	3	0
Repetitive strain injury	2	0
Tendon injury	3	0
Tendon rupture	11	0
Nerve injuries NEC		
Nerve injury	73	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	8	0
Procedural dizziness	28	0
Non-occupational environmental exposures		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	2	0
Non-site specific injuries NEC		
Animal bite	1	0
Arthropod bite	4	0
Arthropod sting	10	0
Bite	1	0
Electric shock	22	0
Fall	193	1
Inflammation of wound	3	0
Injury	10	0
Internal injury	1	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Road traffic accident	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Soft tissue injury	1	0
Tissue injury	1	0
Traumatic haematoma	3	0
Traumatic shock	1	0
Wound	5	0
Wound complication	11	0
Wound haemorrhage	8	0
Wound secretion	2	0
<i>Non-site specific procedural complications</i>		
Incision site erythema	1	0
Incision site haemorrhage	1	0
Incision site oedema	1	0
Incision site pain	9	0
Infusion related reaction	19	0
Injection related reaction	579	0
Needle fatigue	1	0
Post procedural complication	34	0
Post procedural contusion	2	0
Post procedural haematoma	1	0
Procedural hypertension	1	0
Procedural pain	6	0
Procedural site reaction	1	0
Suture related complication	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	1	0
<i>Off label uses</i>		
Off label use	9	0
<i>Overdoses NEC</i>		
Intentional overdose	3	0
Overdose	17	0
<i>Pathways and sources of exposure</i>		
Exposure via body fluid	1	0
Exposure via unknown route	1	0
<i>Peripheral nerve injuries</i>		
Brachial plexus injury	1	0
Median nerve injury	2	0
Sciatic nerve injury	1	0
Ulnar nerve injury	1	0
<i>Poisoning and toxicity</i>		
Alcohol poisoning	3	0
Chemical poisoning	1	0
Metal poisoning	1	0
Poisoning	5	0
Systemic toxicity	1	0
Toxicity to various agents	9	0
<i>Product administration errors and issues</i>		
Accidental overdose	2	0
Accidental underdose	1	0
Contraindicated product administered	4	0
Duplicate therapy error	2	0
Expired product administered	24	0
Extra dose administered	5	0
Inappropriate schedule of product administration	10	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Incomplete course of vaccination	1	0
Incorrect dose administered	4	0
Incorrect product administration duration	1	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	20	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	10	0
Product administered to patient of inappropriate age	13	0
Product administration error	15	0
Product dose omission issue	2	0
Wrong patient received product	1	0
Wrong product administered	12	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	7	0
Product prescribing error	2	0
Product selection errors and issues		
Product selection error	1	0
Product storage errors and issues in the product use system		
Product storage error	2	0
Radiation injuries		
Sunburn	34	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	1	0
Site specific injuries NEC		
Back injury	7	0
Central nervous system injury	1	0
Face crushing	1	0
Face injury	2	0
Head injury	30	0
Limb crushing injury	7	0
Limb injury	172	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		

Case Series Drug Analysis Print

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Report Run Date: 20-May-2021
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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Contusion	2284	0
Nail injury	1	0
Scar	18	0
Scratch	2	0
Skin abrasion	5	0
Skin injury	11	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	1	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	7	0
Burns second degree	7	0
Cold burn	3	0
Thermal burn	43	0
Thermal burns of eye	39	0
Transplantation complications		
Transplant failure	1	0
Underdoses NEC		
Intentional underdose	1	0
Underdose	2	0
Vaccination related complications		
Adverse event following immunisation	3	0
Post vaccination syndrome	1	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	85	0
Injuries SOC TOTAL	5893	2

Case Series Drug Analysis Print

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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	1	0
Antiphospholipid antibodies positive	1	0
Cold agglutinins positive	1	0
DNA antibody positive	1	0
Rheumatoid factor	2	0
Rheumatoid factor increased	1	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	7	0
Blood count abnormal	2	0
Full blood count	6	0
Full blood count abnormal	1	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	11	0
Carbon dioxide increased	1	0
Oxygen consumption	1	0
Oxygen saturation	22	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	160	1
<i>Blood grouping and cross-matching analyses</i>		
Blood group O	2	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	13	0
Blood glucose decreased	35	0
Blood glucose fluctuation	26	0
Blood glucose increased	160	0
Glycosylated haemoglobin increased	2	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	21	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart sounds	14	0
Heart sounds abnormal	5	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	1	0
Myocardial strain	13	0
Stroke volume decreased	1	0
Venous pressure jugular increased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
Prostatic specific antigen increased	2	0
Central nervous system histopathology procedures		
Biopsy brain	1	0
Central nervous system imaging procedures		
Computerised tomogram head	14	0
Magnetic resonance imaging head	37	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	4	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	4	0
Cholesterol analyses		
Blood cholesterol increased	6	0
Low density lipoprotein	1	0
Low density lipoprotein increased	1	0
Very low density lipoprotein decreased	1	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time prolonged	94	0
Bleeding time	4	0
Bleeding time abnormal	3	0
Bleeding time prolonged	3	0
Blood fibrinogen decreased	6	0
Blood fibrinogen increased	1	0
Blood thromboplastin	1	0
Blood thromboplastin abnormal	2	0
Coagulation factor	1	0
Coagulation factor VIII level decreased	1	0
Coagulation time	6	0
Coagulation time prolonged	10	0
Coagulation time shortened	2	0
Fibrin D dimer	1	0
Fibrin D dimer increased	32	0
International normalised ratio	2	0
International normalised ratio abnormal	10	0
International normalised ratio decreased	38	0
International normalised ratio fluctuation	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
International normalised ratio increased	75	0
Prothrombin level increased	1	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
Digestive enzymes		
Amylase increased	1	0
Pancreatic enzymes increased	1	0
ECG investigations		
Cardiac telemetry	1	0
Electrocardiogram	3	0
Electrocardiogram ST segment elevation	2	0
Electrocardiogram ST-T segment abnormal	7	0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	12	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
Exercise electrocardiogram	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	17	0
Faecal analyses NEC		
Faecal calprotectin increased	6	0
Stool analysis abnormal	1	0
Fertility analyses		
Semen volume decreased	2	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	4	0
Gastrointestinal function diagnostic procedures		
Gastric pH	1	0
Gastric pH decreased	1	0
Gastrointestinal stoma output increased	1	0
Swallow study	3	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood gastrin	1	0
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin decreased	2	0
Blood insulin increased	3	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0
Blood viscosity decreased	1	0
Blood viscosity increased	1	0
Haematology test abnormal	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	5	0
Heart rate and pulse investigations		
Brachial pulse decreased	1	0
Heart rate	917	0
Heart rate abnormal	43	0
Heart rate decreased	95	0
Heart rate increased	1781	0
Heart rate irregular	136	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	20	0
Pulse absent	4	0
Pulse pressure abnormal	1	0
Pulse pressure increased	3	0
Pulse waveform abnormal	1	0
Sinus rhythm	5	0
Imaging procedures NEC		
Computerised tomogram	5	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	1	0
Antibody test abnormal	1	0
Antibody test negative	3	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		
Blood test	36	0
Blood test abnormal	40	0
Laboratory test	1	0
Polymerase chain reaction positive	2	0
Liver function analyses		
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	3	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	10	0
Liver function test	3	0
Liver function test abnormal	23	0
Liver function test increased	4	0
Transaminases increased	8	0
Metabolism tests NEC		
Blood ketone body	9	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Ubiquinone	3	0
Ubiquinone decreased	2	0
Urine ketone body present	1	0
Microbiology and serology tests NEC		
Blood culture	2	0
Blood culture negative	1	0
Septic screen	1	0
Mineral and electrolyte analyses		
Blood calcium	1	0
Blood iron	9	0
Blood iron decreased	6	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	5	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	1	0
Sweat test	1	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Bone densitometry	1	0
Skull X-ray	6	0
X-ray of pelvis and hip	1	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	2	0
Swollen joint count increased	2	0
Tender joint count	3	0
Mycobacteria identification and serology		
Interferon gamma release assay positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	14	0
Electromyogram abnormal	1	0
Lumbar puncture	11	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	2	0
Intraocular pressure increased	2	0
Intraocular pressure test	6	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	944	0
Body temperature abnormal	72	0
Body temperature decreased	121	0
Body temperature fluctuation	159	0
Body temperature increased	1035	0
Body temperature normal	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Breath sounds	1	0
Breath sounds abnormal	5	0
Dermatologic examination abnormal	1	0
General physical condition abnormal	1	0
Grip strength	6	0
Grip strength decreased	29	0
Head lag	17	0
Lymph node palpable	5	0
Male genital examination abnormal	1	0
Menstruation normal	1	0
Muscle strength abnormal	2	0
Neurological examination	1	0
Neurological examination normal	1	0
Palpatory finding abnormal	1	0
Psoriasis area severity index decreased	1	0
Respiratory rate	10	0
Respiratory rate decreased	22	0
Respiratory rate increased	69	0
Skin temperature	164	0
Temperature difference of extremities	5	0
Urological examination	1	0
Vital signs measurement	1	0
Weight decreased	128	0
Weight increased	27	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone	1	0
Blood thyroid stimulating hormone decreased	2	0
Blood thyroid stimulating hormone increased	4	0
<i>Platelet analyses</i>		
Platelet count	2	0
Platelet count abnormal	1	0
Platelet count decreased	201	0
Platelet count increased	5	0
Platelet count normal	1	0
<i>Protein analyses NEC</i>		
C-reactive protein abnormal	2	0
C-reactive protein increased	15	0
<i>Red blood cell analyses</i>		
Haematocrit	8	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin	4	0
Haemoglobin decreased	9	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
<i>Renal function analyses</i>		
Blood creatine increased	1	0
Blood creatinine abnormal	1	0
Blood creatinine decreased	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood creatinine increased	1	0
Blood urea	5	0
Blood urea increased	1	0
Glomerular filtration rate decreased	1	0
Reproductive hormone analyses		
Blood oestrogen increased	1	0
Dihydrotestosterone decreased	1	0
False negative pregnancy test	1	0
Human chorionic gonadotropin decreased	1	0
Pregnancy test	10	0
Pregnancy test false positive	1	0
Pregnancy test negative	1	0
Reproductive organ and breast imaging procedures		
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
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	5	0
Pulmonary function test	2	0
Pulmonary function test decreased	2	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	12	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		
Thyroid function test abnormal	1	0
Thyroxine	1	0
Thyroxine abnormal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	2	0
Urinalysis NEC		
Blood urine	26	0
Blood urine present	59	0
Cells in urine	2	0
Crystal urine	3	0
Medication crystals in urine present	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urea urine increased	1	0
Urine analysis	1	0
Urine analysis abnormal	11	0
Urine analysis normal	3	0
pH urine	8	0
pH urine decreased	2	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	41	0
Urine output decreased	17	0
Urine output increased	9	0
Urinary tract imaging procedures		
Cystoscopy	1	0
Vascular auscultatory investigations		
Abdominal bruit	1	0
Carotid bruit	1	0
Vascular imaging procedures NEC		
Venogram	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	3	0
Blood pressure decreased	68	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	3	0
Blood pressure increased	240	0
Blood pressure measurement	80	0
Blood pressure normal	3	0
Blood pressure systolic	1	0
Blood pressure systolic increased	5	0
Capillary nail refill test	1	0
Virus identification and serology		
Coronavirus test	37	0
Cytomegalovirus test	1	0
HIV antibody negative	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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	4	0
SARS-CoV-2 antibody test negative	12	0
SARS-CoV-2 antibody test positive	3	0
SARS-CoV-2 test	17	0
SARS-CoV-2 test false negative	3	0
SARS-CoV-2 test false positive	2	0
SARS-CoV-2 test negative	13	0
SARS-CoV-2 test positive	71	0
Viral test	3	0
Vitamin analyses		
Blood folate	2	0
Blood folate decreased	2	0
Vitamin B12 decreased	1	0
Vitamin D decreased	1	0
Water and electrolyte analyses NEC		
Blood osmolarity	1	0
Volume blood	5	0
White blood cell analyses		
CD4 lymphocytes decreased	1	0
Eosinophil count increased	4	0
Lymphocyte count	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	3	0
Mononuclear cell count abnormal	1	0
Neutrophil count	2	0
Neutrophil count decreased	12	0
Neutrophil count increased	1	0
Neutrophil toxic granulation present	1	0
White blood cell count	12	0
White blood cell count decreased	21	0
White blood cell count increased	6	0
Investigations SOC TOTAL	8459	1

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	35	0
Decreased appetite	5822	1
Diet refusal	2	0
Eating disorder symptom	1	0
Food craving	20	0
Food refusal	34	0
Hyperphagia	7	0
Hypophagia	25	0
Increased appetite	48	0
Salt craving	4	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	5	0
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	66	0
Diabetes mellitus inadequate control	26	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	28	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	105	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	2	0
Fluid imbalance	1	0
Hyperosmolar state	1	1
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	5	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	9	0
<i>Fluid intake increased</i>		
Polydipsia	12	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	6	0
Food intolerance	9	0
Gluten sensitivity	3	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	40	0
Abnormal weight gain	17	0
Cachexia	1	0
Feeding disorder	165	0
Food aversion	52	0
Neonatal insufficient breast milk syndrome	2	0
Obesity	1	0
Overweight	2	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Poor feeding infant	9	0
Starvation	1	0
Underweight	1	0
Weight loss poor	2	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	120	0
Insulin resistance	8	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	86	0
Hypoglycaemia unawareness	3	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	5	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	1	0
Potassium imbalance		
Hyperkalaemia	6	1
Hypokalaemia	4	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	2	0
Hyponatraemia	17	0
Hyponatraemic syndrome	3	1
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	5	0
Total fluid volume decreased		
Dehydration	588	0
Hypovolaemia	1	0
Total fluid volume increased		
Fluid overload	6	0
Fluid retention	50	1
Vitamin deficiencies NEC		

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hypovitaminosis	1	0
Water soluble vitamin deficiencies		
Folate deficiency	3	0
Vitamin B12 deficiency	2	0
Metabolic disorders SOC TOTAL	7540	7

Case Series Drug Analysis Print

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Report Run Date: 20-May-2021
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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	308	0
Arthritis enteropathic	1	0
Arthropathy	23	0
Autoimmune arthritis	8	0
Haemarthrosis	7	0
Oligoarthritis	1	0
Palindromic rheumatism	3	0
Polyarthritis	13	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	7	0
Osteitis	6	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	897	0
Coccydynia	3	0
Pain in jaw	488	0
Pubic pain	1	0
Spinal pain	203	0
<i>Bursal disorders</i>		
Bursitis	87	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	41	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	2	0
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	53	0
Reynold's syndrome	5	0
Scleroderma	2	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	2	0
Limb deformity	4	0
Wrist deformity	1	0
<i>Fractures NEC</i>		
Osteoporotic fracture	1	0
<i>Intervertebral disc disorders NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Intervertebral disc degeneration	1	0
Intervertebral disc protrusion	2	0
Joint related disorders NEC		
Femoroacetabular impingement	2	0
Joint ankylosis	1	0
Joint instability	2	0
Joint laxity	4	0
Joint lock	37	0
Ligament laxity	1	0
Patellofemoral pain syndrome	4	0
Periarthritis	210	0
Rotator cuff syndrome	48	0
Temporomandibular joint syndrome	14	0
Joint related signs and symptoms		
Arthralgia	19415	0
Jaw clicking	4	0
Joint effusion	3	0
Joint noise	32	0
Joint range of motion decreased	3	0
Joint stiffness	348	0
Joint swelling	627	0
Joint vibration	3	0
Joint warmth	25	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	7	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	25	0
Metabolic bone disorders		
Osteopenia	1	0
Osteoporosis	9	0
Muscle infections and inflammations		
Myositis	28	0
Polymyositis	1	0
Muscle pains		
Fibromyalgia	211	0
Myalgia	23940	0
Myalgia intercostal	2	0
Myofascial pain syndrome	19	0
Muscle related signs and symptoms NEC		
Haematoma muscle	2	0
Muscle atrophy	17	0
Muscle discomfort	8	0
Muscle disorder	5	0
Muscle fatigue	810	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	2	0
Muscle spasms	2349	0
Muscle swelling	21	0
Muscle tightness	145	0
Muscle twitching	379	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Muscle tone abnormalities</i>		
Muscle rigidity	42	0
Nuchal rigidity	14	0
Torticollis	8	0
Trismus	49	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1592	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Extremity contracture	1	0
Infantile back arching	1	0
Limb mass	10	0
Mandibular mass	1	0
Mastication disorder	2	0
Mobility decreased	92	0
Muscle contracture	2	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	1832	0
Posture abnormal	1	0
Somatic dysfunction	1	0
Weight bearing difficulty	5	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	2	0
Head deformity	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Connective tissue inflammation	2	0
Dactylitis	2	0
Fasciitis	1	0
Plantar fasciitis	6	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Amplified musculoskeletal pain syndrome	1	0
Back pain	4860	0
Flank pain	62	0
Growing pains	8	0
Limb discomfort	1865	0
Musculoskeletal chest pain	345	0
Musculoskeletal discomfort	108	0
Musculoskeletal pain	57	0
Neck pain	2495	0
Pain in extremity	17768	0
Rheumatic disorder	15	0
<i>Myopathies</i>		
Compartment syndrome	3	0
Muscle necrosis	1	0
Myopathy	4	0
Rhabdomyolysis	7	1
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	36	0
Spinal osteoarthritis	4	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	24	0
<i>Rheumatoid arthropathies</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Felty's syndrome	1	0
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	119	0
Still's disease	4	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	47	0
Clubbing	1	0
Fistula	1	0
Groin pain	168	0
Neck mass	15	0
Soft tissue disorder	2	0
Soft tissue mass	2	0
Soft tissue swelling	5	0
<i>Spine and neck deformities</i>		
Kyphosis	4	0
Scoliosis	2	0
Spinal stenosis	2	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	22	0
Arthritis reactive	20	0
Axial spondyloarthritis	1	0
Spondylitis	2	0
<i>Synovial disorders</i>		
Synovial cyst	5	0
Synovitis	11	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon discomfort	3	0
Tendon disorder	4	0
Tendon pain	28	0
Tendonitis	50	0
Tenosynovitis	1	0
Tenosynovitis stenosaurs	1	0
Trigger finger	18	0
Muscle & tissue disorders SOC TOTAL	82847	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
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	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	35	0
Breast cancer male	2	0
Breast cancer metastatic	1	0
Breast cancer stage III	1	0
Intraductal proliferative breast lesion	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	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	1	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	1	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	2	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>Leukaemias NEC</i>		
Leukaemia	1	0
Leukaemia recurrent	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	6	0
<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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Squamous cell carcinoma of the oral cavity	1	0
Lymphomas unspecified NEC		
Lymphoma	12	0
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Lymphoproliferative disorder in remission	1	0
Mediastinal neoplasms malignancy unspecified NEC		
Good syndrome	1	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to central nervous system	1	1
Metastases to lung	1	1
Metastases to unknown and unspecified sites		
Metastasis	3	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms benign site unspecified NEC		
Fibroma	1	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma	2	0
Metastatic neoplasm	2	0
Neoplasm malignant	5	1
Squamous cell carcinoma	1	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm recurrence	6	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	2	0
Meningioma	2	0
Neuromas		
Acoustic neuroma	3	0
Non-small cell neoplasms malignant of the respiratory tract cell type specified		
Lung adenocarcinoma	1	1
Ocular neoplasms benign		
Eye naevus	3	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oesophageal carcinoma	4	0
Oesophageal squamous cell carcinoma	1	0
Oncologic complications and emergencies		
Cancer fatigue	4	0
Cancer pain	1	0
Intracranial tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	2	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	5	0
Ovarian cancer stage IV	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	3	0
Plasma cell myelomas		
Plasma cell myeloma	1	0
Prostatic neoplasms malignant		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Prostate cancer	7	0
Renal neoplasms malignant		
Clear cell renal cell carcinoma	3	0
Metastatic renal cell carcinoma	1	0
Renal cancer	1	0
Respiratory tract and pleural neoplasms malignancy unspecified NEC		
Maxillofacial sinus neoplasm	1	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	4	0
Lung cancer metastatic	1	0
Lung neoplasm malignant	8	0
Throat cancer	1	0
Salivary gland neoplasms malignant		
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
Skin melanomas (excl ocular)		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	2	0
Malignant melanoma in situ	1	0
Skin neoplasms benign		
Acrochordon	2	0
Haemangioma of skin	9	0
Melanocytic naevus	2	0
Skin papilloma	13	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	1	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	2	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Knuckle pads	1	0
Lipoma	4	0
Uterine neoplasms benign		
Uterine leiomyoma	3	0
Uterine neoplasms malignant NEC		
Uterine cancer	1	0
Neoplasms SOC TOTAL	228	4

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	17	0
Extensor plantar response	1	0
Hyperreflexia	4	0
Hyporeflexia	10	0
Poor sucking reflex	1	0
Reflexes abnormal	1	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	20	0
<i>Absence seizures</i>		
Petit mal epilepsy	26	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	3	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	248	4
Miller Fisher syndrome	13	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	1	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	2	0
Basal ganglia stroke	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	1	0
Carotid artery thrombosis	8	0
Cerebellar haemorrhage	4	0
Cerebellar infarction	4	0
Cerebellar stroke	9	0
Cerebral artery embolism	7	0
Cerebral artery occlusion	3	0
Cerebral artery thrombosis	8	0
Cerebral haematoma	12	1
Cerebral haemorrhage	125	33
Cerebral infarction	62	3
Cerebral ischaemia	3	0
Cerebral thrombosis	28	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	751	32
Embolic stroke	16	0
Haemorrhage intracranial	42	7
Haemorrhagic cerebral infarction	2	1
Haemorrhagic stroke	26	4
Haemorrhagic transformation stroke	5	2

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Intracranial haematoma	6	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	2	0
Ischaemic stroke	88	3
Lacunar infarction	4	0
Lacunar stroke	17	0
Spinal cord haematoma	2	0
Subarachnoid haemorrhage	75	4
Thalamus haemorrhage	6	0
Thrombotic stroke	8	0
Vertebral artery occlusion	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	2	0
Central nervous system inflammation	9	0
Neurosarcoidosis	2	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	2	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	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	157	17
Cerebral venous thrombosis	32	3
Superior sagittal sinus thrombosis	22	3
Transverse sinus thrombosis	4	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	4	0
Cervicobrachial syndrome	5	0
Choreiform movements		
Chorea	3	0
Choreoathetosis	1	0
Sydenham's chorea	1	0
Chronic polyneuropathies		
Demyelinating polyneuropathy	6	0
Diabetic neuropathy	2	0
Coma states		
Coma	11	0
Diabetic coma	3	0
Coordination and balance disturbances		
Ataxia	26	0
Balance disorder	650	0
Cerebellar ataxia	1	0
Coordination abnormal	93	0
Dysdiadochokinesis	1	0
Dysstasia	82	0
Hand-eye coordination impaired	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nystagmus	15	0
Cortical dysfunction NEC		
Alexia	3	0
Aphasia	98	0
Apraxia	1	0
Dysgraphia	4	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	16	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	7	0
Demyelination	12	0
Neuromyelitis optica spectrum disorder	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	10	0
Consciousness fluctuating	4	0
Depressed level of consciousness	69	0
Lethargy	4120	0
Loss of consciousness	851	0
Postictal state	1	0
Sedation	11	0
Somnolence	1561	1
Stupor	8	0
Syncope	2077	0
Disturbances in sleep phase rhythm		
Advanced sleep phase	1	0
Circadian rhythm sleep disorder	3	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	24	0
Clumsiness	38	0
Dyskinesia	91	0
Extrapyramidal disorder	18	0
Fine motor delay	2	0
Fine motor skill dysfunction	9	0
Hyperkinesia	26	0
Hypokinesia	44	0
Meige's syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Motor dysfunction	11	0
Movement disorder	63	0
Psychomotor hyperactivity	30	0
<i>Dystonias</i>		
Dystonia	15	0
Dystonic tremor	3	0
Opisthotonus	4	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	4	0
<i>Encephalopathies NEC</i>		
Autoimmune encephalopathy	3	0
Encephalopathy	4	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	2	0
<i>Encephalopathies toxic and metabolic</i>		
Hepatic encephalopathy	2	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	5	0
Microvascular cranial nerve palsy	1	0
VIth nerve paralysis	7	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	341	0
Facial nerve disorder	4	0
Facial paralysis	203	0
Facial paresis	109	0
Facial spasm	23	0
Oculofacial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	64	0
<i>Headaches NEC</i>		
Cervicogenic headache	5	0
Cluster headache	583	0
Cold-stimulus headache	64	0
Drug withdrawal headache	14	0
Exertional headache	10	0
External compression headache	3	0
Headache	70313	4
Medication overuse headache	14	0
New daily persistent headache	17	0
Occipital neuralgia	15	0
Ophthalmoplegic migraine	1	0
Post-traumatic headache	2	0
Primary cough headache	2	0
Primary headache associated with sexual activity	10	0
Sinus headache	820	0
Tension headache	1215	0
Thunderclap headache	38	0
Vascular headache	66	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	9	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	5	0

Case Series Drug Analysis Print

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Report Run Date: 20-May-2021
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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Increased intracranial pressure disorders</i>		
Brain compression	2	0
Brain oedema	21	1
Cerebrospinal fluid circulation disorder	3	0
Idiopathic intracranial hypertension	5	0
Intracranial pressure increased	18	0
<i>Intellectual disabilities</i>		
Intellectual disability	9	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Lumbar radiculopathy	2	0
Sciatica	142	0
<i>Memory loss (excl dementia)</i>		
Amnesia	215	0
Memory impairment	208	0
Transient global amnesia	16	0
<i>Meningitis NEC</i>		
Meningitis noninfective	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	122	1
Disturbance in attention	506	0
Judgement impaired	3	0
Mental impairment	99	0
<i>Migraine headaches</i>		
Basilar migraine	4	0
Hemiplegic migraine	27	0
Migraine	6021	0
Migraine with aura	275	0
Migraine without aura	37	0
Ophthalmic migraine	9	0
Retinal migraine	53	0
Status migrainosus	2	0
Typical aura without headache	13	0
Vestibular migraine	17	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	19	0
Cubital tunnel syndrome	1	0
Diabetic mononeuropathy	1	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	2	0
Nerve compression	31	0
Peroneal nerve palsy	8	0
Piriformis syndrome	1	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
<i>Motor neurone diseases</i>		
Motor neurone disease	1	0
<i>Multiple sclerosis acute and progressive</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Band sensation	4	0
Multiple sclerosis	46	0
Multiple sclerosis relapse	37	0
Relapsing multiple sclerosis	1	0
Uhthoff's phenomenon	4	0
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	29	0
Serotonin syndrome	1	0
Stiff leg syndrome	7	0
Myelitis (incl infective)		
Myelitis transverse	60	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	160	0
Narcolepsy	13	0
Nervous system cysts and polyps		
Pineal gland cyst	1	0
Nervous system disorders NEC		
Brain stem syndrome	2	0
Cerebral disorder	1	0
Nervous system disorder	31	0
Neurotoxicity	1	0
Psychomotor skills impaired	4	0
Neurologic visual problems NEC		
Hemianopia	6	0
Hemianopia homonymous	1	0
Tunnel vision	14	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Dizziness	18511	0
Dizziness exertional	78	0
Dizziness postural	1843	1
Drooling	14	0
Exaggerated startle response	3	0
Fontanelle bulging	3	0
Head discomfort	507	0
Hyporesponsive to stimuli	2	0
Inability to crawl	1	0
Infant irritability	5	0
Intracranial hypotension	2	0
Meningism	2	0
Myoclonus	24	0
Neurological decompensation	4	0
Neurological symptom	79	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	26	0
Pleocytosis	2	0
Presyncope	511	0
Sensory overload	10	0
Slow response to stimuli	5	0
Tongue biting	8	0
Unresponsive to stimuli	79	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neuromuscular disorders NEC		
Muscle contractions involuntary	26	0
Muscle spasticity	19	0
Neuromuscular pain	5	0
Neuromyopathy	3	0
Neuromyotonia	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	9	0
Myasthenia gravis crisis	3	0
Olfactory nerve disorders		
Anosmia	233	0
Hyposmia	10	0
Parosmia	317	0
Optic nerve disorders NEC		
Optic neuritis	31	0
Paraesthesias and dysaesthesias		
Anaesthesia	3	0
Burning feet syndrome	21	0
Burning sensation	674	0
Burning sensation mucosal	3	0
Dysaesthesia	6	0
Formication	53	0
Hand-arm vibration syndrome	1	0
Hemianaesthesia	3	0
Hemiparaesthesia	2	0
Hyperaesthesia	222	0
Hypoaesthesia	4153	0
Lhermitte's sign	1	0
Paraesthesia	7095	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	23	0
Hemiparesis	71	0
Hemiplegia	24	0
Monoparesis	70	0
Monoplegia	95	0
Paralysis	233	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		
Freezing phenomenon	140	0
Parkinson's disease	15	0
Parkinsonism	10	0
Reduced facial expression	4	0
Vascular parkinsonism	1	0
Partial complex seizures		
Dreamy state	17	0
Focal dyscognitive seizures	5	0
Temporal lobe epilepsy	3	0
Partial simple seizures NEC		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Autonomic seizure	1	0
Simple partial seizures	4	0
Peripheral neuropathies NEC		
Autoimmune neuropathy	2	0
Axonal neuropathy	1	0
Neuralgic amyotrophy	2	0
Neuritis	8	0
Neuropathy peripheral	140	0
Peripheral motor neuropathy	1	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	7	0
Small fibre neuropathy	2	0
Thoracic outlet syndrome	1	0
Seizures and seizure disorders NEC		
Alcoholic seizure	1	0
Atonic seizures	9	0
Change in seizure presentation	3	0
Clonic convulsion	8	0
Drug withdrawal convulsions	2	0
Epilepsy	210	0
Epileptic aura	2	0
Febrile convulsion	79	0
Migraine-triggered seizure	1	0
Myoclonic epilepsy	4	0
Partial seizures	45	0
Psychogenic seizure	5	0
Seizure	952	2
Seizure anoxic	3	0
Seizure cluster	4	0
Seizure like phenomena	2	0
Status epilepticus	106	3
Tonic clonic movements	2	0
Tonic convulsion	30	0
Sensory abnormalities NEC		
Ageusia	877	0
Allodynia	51	0
Aura	18	0
Central pain syndrome	2	0
Complex regional pain syndrome	8	0
Dysgeusia	1697	0
Electric shock sensation	69	0
Hypogeusia	5	0
Intercostal neuralgia	1	0
Loss of proprioception	2	0
Neuralgia	960	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	17	0
Post herpetic neuralgia	8	0
Restless arm syndrome	11	0
Restless legs syndrome	307	0
Sensory disturbance	81	0
Sensory loss	153	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Taste disorder	426	0
Vibratory sense increased	1	0
Visual perseveration	1	0
Sleep disturbances NEC		
Microsleep	2	0
Sleep deficit	39	0
Speech and language abnormalities		
Dysarthria	280	0
Incoherent	14	0
Language disorder	2	0
Muscle tension dysphonia	1	0
Slow speech	21	0
Speech disorder	57	0
Spinal cord and nerve root disorders NEC		
Cauda equina syndrome	4	0
Myelopathy	3	0
Radicular pain	1	0
Radiculitis brachial	11	0
Radiculopathy	2	0
Spinal cord disorder	3	0
Structural brain disorders NEC		
Brain injury	17	1
Cerebral mass effect	5	0
Intracranial mass	3	0
White matter lesion	1	0
Transient cerebrovascular events		
Transient ischaemic attack	324	0
Tremor (excl congenital)		
Action tremor	2	0
Asterixis	1	0
Essential tremor	4	0
Head titubation	13	0
Intention tremor	1	0
Postural tremor	1	0
Resting tremor	5	0
Tremor	8772	3
Trigeminal disorders		
Facial neuralgia	28	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	59	0
Trigeminal neuritis	1	0
Trigeminal palsy	1	0
Vagus nerve disorders		
Vagus nerve paralysis	1	0
Vertigos NEC		
Vertigo CNS origin	2	0
Nervous system disorders SOC TOTAL	145826	142

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	63	1
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
Foetal hypokinesia	2	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	32	0
Pelvic girdle pain	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Pregnancy	18	0
Uterine contractions during pregnancy	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	6	0
<i>Stillbirth and foetal death</i>		
Stillbirth	3	1
<i>Umbilical cord complications</i>		
Umbilical cord abnormality	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	4	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	4	0
Pregnancy conditions SOC TOTAL	160	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	32	0
Undersensing	3	0
<i>Device physical property and chemical issues</i>		
Needle issue	4	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	1	0
<i>Product label issues</i>		
Product label issue	2	0
<i>Product packaging issues</i>		
Product container issue	1	0
<i>Product physical issues</i>		
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 origin unknown	2	0
Product quality issue	1	0
Suspected product quality issue	2	0
null SOC TOTAL	92	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	13	0
Breath holding	3	0
Staring	8	0
<i>Abnormal food elimination</i>		
Self-induced vomiting	1	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	5	0
<i>Affect alterations NEC</i>		
Affect lability	6	0
Constricted affect	5	0
Flat affect	9	0
Inappropriate affect	15	0
<i>Amnesic symptoms</i>		
Paramnesia	3	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
Generalised anxiety disorder	2	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	167	0
Anxiety	797	0
Immunisation anxiety related reaction	1	0
Nervousness	517	0
Stress	81	0
Tension	52	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	12	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	10	0
Asocial behaviour	1	0
Aversion	1	0
Disinhibition	1	0
Impatience	2	0
Indifference	8	0
Paranoia	30	0
Personality change	4	0
Social avoidant behaviour	4	0
Soliloquy	2	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	12	0
Distractibility	1	0
Mental fatigue	379	0
<i>Communications disorders</i>		
Communication disorder	3	0
Mutism	2	0
Speech sound disorder	2	0
<i>Confusion and disorientation</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Confusional state	1633	1
Disorientation	598	0
Decreased physical activity levels		
Catatonia	2	0
Deliria		
Delirium	427	0
Delirium febrile	3	0
Delusional disorders		
Alice in wonderland syndrome	3	0
Delusional symptoms		
Delusion	36	0
Delusion of parasitosis	1	0
Mixed delusion	1	0
Thought withdrawal	1	0
Depressive disorders		
Agitated depression	3	0
Depression	429	0
Depression suicidal	12	0
Major depression	19	0
Mixed anxiety and depressive disorder	1	0
Dissociative states		
Depersonalisation/derealisation disorder	14	0
Dissociation	55	0
Dissociative disorder	1	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	30	0
Insomnia	2585	0
Middle insomnia	67	0
Terminal insomnia	8	0
Dyssomnias		
Dyssomnia	4	0
Poor quality sleep	583	0
Eating disorders NEC		
Eating disorder	6	0
Emotional and mood disturbances NEC		
Anger	61	0
Dysphoria	2	0
Emotional disorder	76	0
Emotional distress	57	0
Emotional poverty	2	0
Euphoric mood	57	0
Frustration tolerance decreased	4	0
Irritability	243	0
Mood altered	54	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	1	0
Agoraphobia	3	0
Fear	24	0
Fear of death	9	0
Fear of disease	2	0
Fear of eating	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Fear of falling	3	0
Fear of injection	2	0
Fear of open spaces	1	0
Performance fear	1	0
Phobia	2	0
Phonophobia	3	0
Fluctuating mood symptoms		
Mood swings	52	0
Hallucinations (excl sleep-related)		
Hallucination	813	0
Hallucination, auditory	34	0
Hallucination, olfactory	7	0
Hallucination, tactile	1	0
Hallucination, visual	46	0
Hallucinations, mixed	7	0
Impulse control disorders		
Impulse-control disorder	2	0
Impulsive behaviour	1	0
Intermittent explosive disorder	1	0
Increased physical activity levels		
Restlessness	428	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Emotional disorder of childhood	1	0
Mental disorders NEC		
Mental disorder	8	0
Mental status changes	3	0
Mental disorders due to a general medical condition NEC		
Neuropsychiatric symptoms	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	12	0
Depressed mood	457	0
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	16	0
Negative thoughts	6	0
Sense of a foreshortened future	1	0
Tearfulness	89	0
Mood alterations with manic symptoms		
Hypomania	1	0
Mania	26	0
Mood disorders NEC		
Affective disorder	2	0
Apathy	42	0
Listless	109	0
Mood disorder due to a general medical condition	1	0
Substance-induced mood disorder	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Sleep attacks	1	0
Obsessive-compulsive disorders and symptoms		
Body dysmorphic disorder	1	0
Compulsive shopping	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Dermatillomania	1	0
Obsessive thoughts	2	0
Obsessive-compulsive disorder	1	0
Orgasmic disorders and disturbances		
Anorgasmia	2	0
Female orgasmic disorder	1	0
Orgasm abnormal	1	0
Orgasmic sensation decreased	4	0
Premature ejaculation	2	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	231	0
Panic disorder	2	0
Panic reaction	28	0
Paraphilias and paraphilic disorders		
Fetishism	2	0
Parasomnias		
Abnormal dreams	316	0
Abnormal sleep-related event	1	0
Confusional arousal	2	0
Exploding head syndrome	6	0
Nightmare	395	0
Parasomnia	1	0
Rapid eye movements sleep abnormal	3	0
Sleep inertia	1	0
Sleep talking	15	0
Sleep terror	50	0
Sleep-related eating disorder	2	0
Somnambulism	7	0
Perception disturbances NEC		
Autoscopy	20	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
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	45	0
Psychiatric symptoms NEC		
Helplessness	2	0
Hypervigilance	13	0
Psychiatric symptom	5	0
Psychological trauma	3	0
Psychotic disorder NEC		
Acute psychosis	2	0
Psychotic behaviour	1	0
Psychotic disorder	27	0
Psychotic symptom	1	0
Rebound psychosis	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Schizoaffective and schizophreniform disorders</i>		
Schizoaffective disorder	1	0
<i>Schizophrenia NEC</i>		
Schizophrenia	1	0
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	3	0
<i>Sexual desire disorders</i>		
Hypersexuality	1	0
Libido decreased	12	0
Libido increased	5	0
Loss of libido	31	0
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	320	0
Sleep disorder due to general medical condition, insomnia type	2	0
<i>Somatic symptom disorders</i>		
Conversion disorder	12	0
Habit cough	31	0
Illness anxiety disorder	1	0
Psychogenic tremor	1	0
Somatic symptom disorder	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	15	0
Logorrhoea	2	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	21	0
Lack of spontaneous speech	2	0
<i>Stereotypies and automatisms</i>		
Bruxism	25	0
Head banging	31	0
Waxy flexibility	2	0
<i>Stress disorders</i>		
Acute stress disorder	2	0
Burnout syndrome	8	0
Hyperarousal	3	0
Post-traumatic stress disorder	11	0
<i>Substance related and addictive disorders</i>		
Alcohol abuse	2	0
Alcohol use disorder	2	0
Alcoholism	3	0
Dependence	1	0
Drug dependence	1	0
Substance abuse	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	4	1
Intentional self-injury	7	0
Self-injurious ideation	2	0
Suicidal behaviour	2	0
Suicidal ideation	83	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Suicide attempt	12	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	75	0
Confabulation	1	0
Impaired reasoning	2	0
Intrusive thoughts	3	0
Morbid thoughts	4	0
Tachyphrenia	20	0
Thinking abnormal	20	0
Thought blocking	3	0
<i>Tic disorders</i>		
Tic	9	0
Psychiatric disorders SOC TOTAL	13534	2

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	5	0
Bladder irritation	6	0
Bladder pain	45	0
Bladder spasm	1	0
Dysuria	62	0
Incontinence	67	0
Micturition disorder	3	0
Micturition frequency decreased	1	0
Micturition urgency	88	0
Mixed incontinence	1	0
Pollakiuria	234	0
Urethral pain	2	0
Urge incontinence	2	0
Urinary hesitation	5	0
Urinary incontinence	88	0
Urinary retention	60	0
Urine flow decreased	9	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	14	0
Urinary bladder haemorrhage	8	1
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	5	0
Cystitis noninfective	2	0
Lupus cystitis	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	3	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	2	0
Nephrotic syndrome	12	0
<i>Myoneurogenic bladder disorders</i>		
Automatic bladder	1	0
Bladder dysfunction	2	0
Hypertonic bladder	13	0
Loss of bladder sensation	10	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	42	1
Anuria	4	0
Chronic kidney disease	7	0
Oliguria	10	0
Renal failure	15	2
Renal impairment	10	0
Renal injury	4	0
Renal hypertension and related conditions		
Hypertensive nephropathy	1	0
Renal lithiasis		
Nephrolithiasis	9	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 vein embolism	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	84	0
Glycosuria	1	0
Haematuria	48	0
Microalbuminuria	1	0
Proteinuria	6	0
Urine abnormality	17	0
Urine odour abnormal	18	0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	0
Urinary tract signs and symptoms NEC		
Haemorrhage urinary tract	37	0
Nocturia	16	0
Polyuria	24	0
Renal colic	2	0
Renal pain	790	0
Urinary tract discomfort	1	0
Urinary tract pain	10	0
Renal & urinary disorders SOC TOTAL	1971	4

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	5	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	5	0
Breast mass	33	0
Gynaecomastia	5	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	7	0
Breast engorgement	4	0
Breast haemorrhage	1	0
Breast induration	1	0
Breast oedema	1	0
Breast pain	296	0
Breast swelling	44	0
Breast tenderness	38	0
Nipple pain	29	0
Nipple swelling	1	0
<i>Cervix disorders NEC</i>		
Cervix haemorrhage uterine	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation delayed	1	0
Ejaculation disorder	3	0
Ejaculation failure	2	0
Erectile dysfunction	40	0
Erection increased	4	0
Organic erectile dysfunction	17	0
Painful erection	1	0
Priapism	2	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	2	0
Suppressed lactation	17	0
<i>Menopausal effects NEC</i>		
Artificial menopause	2	0
Menopausal disorder	1	0
Menopausal symptoms	21	0
Menopause delayed	2	0
Premature menopause	6	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	95	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Abnormal withdrawal bleeding	1	0
Dysmenorrhoea	203	0
Intermenstrual bleeding	167	0
Menstrual discomfort	1	0
Menstrual disorder	317	0
Menstruation irregular	416	0
Premenstrual pain	15	0
Premenstrual syndrome	6	0
Retrograde menstruation	1	0
Withdrawal bleed	6	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	121	0
Hypomenorrhoea	96	0
Menstruation delayed	546	0
Oligomenorrhoea	25	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	874	0
Menometrorrhagia	2	0
Polymenorrhoea	111	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	6	0
Ovarian cyst ruptured	1	0
Polycystic ovaries	6	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovarian enlargement	1	0
Ovarian haemorrhage	3	0
Ovarian necrosis	1	0
Ovarian vein thrombosis	2	0
Ovulation pain	12	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	20	0
Pelvic haematoma	1	0
Pelvic haemorrhage	9	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	1	0
Penile exfoliation	1	0
Penile haemorrhage	4	0
Penile oedema	2	0
Penile pain	1	0
Penis disorder	5	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

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	2	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Female genital tract fistula	1	0
Genital blister	3	0
Genital haemorrhage	8	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	2	0
Genital lesion	1	0
Genital paraesthesia	1	0
Genital ulceration	12	0
Perineal disorder	1	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	6	0
Genital discomfort	3	0
Genital erythema	1	0
Genital pain	3	0
Genital rash	2	0
Pelvic discomfort	2	0
Pelvic pain	103	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 male	1	0
Sexual dysfunction	6	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haematospermia	7	0
Semen discolouration	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	4	0
Testicular mass	1	0
Testicular oedema	2	0
Testicular pain	82	0
Testicular retraction	1	0
Testicular swelling	11	0
<i>Testicular and epididymal neoplasms</i>		
Epididymal cyst	1	0
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	3	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Endometriosis	29	0
Metrorrhoea	1	0
Uterine enlargement	1	0
Uterine haemorrhage	23	0
Uterine pain	5	0
Uterine neoplasms		
Uterine polyp	2	0
Uterine tone disorders		
Uterine spasm	9	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	1	0
Vaginal cyst	7	0
Vulvovaginal disorders NEC		
Vaginal disorder	1	0
Vaginal haemorrhage	435	0
Vaginal ulceration	6	0
Vulval disorder	2	0
Vulval haemorrhage	10	0
Vulval ulceration	4	0
Vulvovaginal ulceration	2	0
Vulvovaginal signs and symptoms		
Enlarged clitoris	1	0
Labia enlarged	2	0
Vaginal discharge	35	0
Vaginal lesion	4	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	7	0
Vulvovaginal discomfort	7	0
Vulvovaginal dryness	3	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	20	0
Vulvovaginal pruritus	8	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	4	0
Reproductive & breast disorders SOC TOTAL	4664	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	10	0
Apnoeic attack	1	0
Dyspnoea	5411	6
Dyspnoea at rest	12	0
Dyspnoea exertional	34	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	79	0
Hypopnoea	185	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	7	0
Orthopnoea	3	0
Respiration abnormal	79	0
Respiratory arrest	19	0
Respiratory distress	8	0
Respiratory fatigue	6	0
Sleep apnoea syndrome	19	0
Tachypnoea	32	0
<i>Bronchial conditions NEC</i>		
Bronchiectasis	14	0
<i>Bronchospasm and obstruction</i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	451	0
Asthma exercise induced	1	0
Asthma late onset	1	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	1	0
Asthmatic crisis	5	0
Bronchitis chronic	1	0
Bronchospasm	14	0
Chronic obstructive pulmonary disease	27	2
Cough variant asthma	6	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	482	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Hypercapnia	1	0
Hypoxia	57	1
<i>Coughing and associated symptoms</i>		
Allergic cough	4	0
Cough	3134	0
Haemoptysis	94	0
Productive cough	148	0
Sputum discoloured	7	0
Sputum increased	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Reflux laryngitis	2	0
Vocal cord thickening	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Laryngospasm	2	0
Stridor	17	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	2	0
Eosinophilic pneumonia	1	0
Pneumonia aspiration	21	4
Pneumonitis	19	1
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	37	0
Lower respiratory tract congestion	4	0
Lung opacity	5	0
Pleuritic pain	27	0
Pulmonary haemorrhage	5	1
Pulmonary pain	173	0
Rales	2	0
<i>Mediastinal disorders</i>		
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	384	0
Nasal inflammation	7	0
Rhinitis allergic	20	0
Rhinitis perennial	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1624	0
Intranasal hyposaesthesia	1	0
Nasal crusting	6	0
Nasal cyst	2	0
Nasal disorder	4	0
Nasal dryness	51	0
Nasal mucosal discolouration	1	0
Nasal odour	2	0
Nasal oedema	10	0
Nasal polyps	1	0
Nasal pruritus	7	0
Nasal septum deviation	1	0
Nasal septum perforation	1	0
Nasal ulcer	3	0
<i>Neonatal hypoxic conditions</i>		
Cyanosis neonatal	1	0
Gasping syndrome	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Paranasal sinus haemorrhage	5	0
Paranasal sinus hypersecretion	1	0
Paranasal sinus inflammation	2	0
Sinonasal obstruction	8	0
Sinus congestion	71	0
Sinus disorder	11	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	2	0
Emphysema	2	0
Idiopathic pulmonary fibrosis	1	0
Interstitial lung disease	12	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
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	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	31	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	11	0
Pharyngeal paraesthesia	28	0
Pharyngeal swelling	222	0
Pharyngeal ulceration	14	0
Tonsillar disorder	1	0
Tonsillar erythema	5	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	54	0
Tonsillar inflammation	3	0
Tonsillar ulcer	2	0
<i>Pleural conditions NEC</i>		
Pleural thickening	1	0
<i>Pleural infections and inflammations</i>		
Lupus pleurisy	1	0
Pleurisy	34	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	20	0
Pneumothorax	4	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	19	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	1	0
Pulmonary embolism	1044	79
Pulmonary infarction	9	1
Pulmonary thrombosis	17	1
Pulmonary venous thrombosis	2	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
Respiratory failure	16	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	8	0
Diaphragmalgia	13	0
Painful respiration	6	0
Respiratory symptom	16	0
Suffocation feeling	4	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Respiratory tract disorders NEC</i>		
Aspiration	8	2
Chronic respiratory disease	2	1
Lung disorder	6	0
Pulmonary mass	3	0
Respiratory disorder	5	0
Respiratory tract congestion	6	0
Respiratory tract haemorrhage	1	0
Respiratory tract irritation	8	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	73	0
Catarrh	53	0
Choking	15	0
Choking sensation	8	0
Dry throat	228	0
Dysphonia	110	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	17	0
Laryngeal pain	1	0
Nasal discharge discolouration	2	0
Nasal discomfort	96	0
Oropharyngeal blistering	22	0
Oropharyngeal discomfort	29	0
Oropharyngeal pain	3540	0
Paranasal sinus discomfort	55	0
Rhinalgia	31	0
Rhinorrhoea	1438	0
Sinus pain	512	0
Sneezing	400	0
Snoring	5	0
Throat clearing	5	0
Throat irritation	169	0
Throat lesion	1	0
Throat tightness	169	0
Upper airway obstruction	1	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	23	0
Yawning	60	0
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary artery occlusion	1	0
Pulmonary vascular disorder	1	0
Respiratory disorders SOC TOTAL	21695	104

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	67	0
Acne cystic	3	0
Dermatitis acneiform	6	0
<i>Alopecias</i>		
Alopecia	191	0
Alopecia areata	12	0
Alopecia totalis	1	0
Alopecia universalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	3	0
Madarosis	2	0
<i>Angioedemas</i>		
Angioedema	268	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Cold sweat	1495	0
Hyperhidrosis	8129	0
Hypohidrosis	3	0
Miliaria	173	0
Night sweats	1649	0
Sweat discolouration	2	0
Sweat gland disorder	1	0
<i>Bullous conditions</i>		
Blister	386	0
Blister rupture	6	0
Blood blister	64	0
Dermatitis bullous	12	0
Dermatitis herpetiformis	2	0
Erythema multiforme	31	0
Oedema blister	1	0
Pemphigoid	15	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	2	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	343	0
Macule	8	0
Myxoid cyst	1	0
Pain of skin	817	0
Papule	79	0
Peau d'orange	3	0
Scab	19	0
Scar pain	10	0
Sensitive skin	518	0
Skin burning sensation	460	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin discolouration	136	0
Skin discomfort	3	0
Skin disorder	20	0
Skin fissures	9	0
Skin fragility	1	0
Skin indentation	11	0
Skin induration	14	0
Skin laxity	1	0
Skin lesion	36	0
Skin necrosis	4	0
Skin odour abnormal	41	0
Skin plaque	3	0
Skin reaction	209	0
Skin sensitisation	81	0
Skin swelling	76	0
Skin texture abnormal	1	0
Skin tightness	27	0
Skin warm	513	0
Skin weeping	4	0
Sticky skin	6	0
Transient acantholytic dermatosis	1	0
Yellow skin	25	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	1	0
Dermatitis	145	0
Dermatitis allergic	246	0
Dermatitis atopic	15	0
Dermatitis contact	15	0
Dermatitis diaper	2	0
Dyshidrotic eczema	6	0
Eczema	189	0
Eczema asteatotic	10	0
Eczema nummular	2	0
Eczema weeping	2	0
Hand dermatitis	5	0
Intertrigo	2	0
Perioral dermatitis	3	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	7	0
Skin irritation	112	0
Stasis dermatitis	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	29	0
Drug reaction with eosinophilia and systemic symptoms	12	0
Fixed eruption	4	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	2889	0
Erythema ab igne	1	0
Palmar erythema	4	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis exfoliative generalised	4	0
Exfoliative rash	13	0
Skin exfoliation	102	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	2	0
<i>Hyperpigmentation disorders</i>		
Melanoderma	2	0
Skin hyperpigmentation	1	0
Solar lentigo	4	0
<i>Hypertrichoses</i>		
Hypertrichosis	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	7	0
Skin hypopigmentation	1	0
Vitiligo	9	0
<i>Lipodystrophies</i>		
Lipoatrophy	2	0
Lipohypertrophy	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail bed disorder	2	0
Nail bed tenderness	1	0
Nail discolouration	9	0
Nail disorder	1	0
Nail hypertrophy	1	0
Nail necrosis	1	0
Nail pigmentation	1	0
Nail pitting	1	0
Nail ridging	4	0
Onychalgia	4	0
Onychoclasia	7	0
Onycholysis	1	0
Onychomadesis	1	0
Splinter haemorrhages	1	0
<i>Panniculitides</i>		
Erythema nodosum	21	0
Panniculitis	3	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	16	0
Lichen sclerosus	3	0
Parapsoriasis	1	0
Pityriasis rosea	29	0
Pityriasis rubra pilaris	2	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photodermatosis	1	0
Photosensitivity reaction	127	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	10	0
<i>Pilar disorders NEC</i>		
Hair colour changes	5	0
Hair disorder	1	0

Case Series Drug Analysis Print

Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 20-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 19-May-2021 18:30:09
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hair growth abnormal	5	0
Hair texture abnormal	4	0
Piloerection	86	0
Pseudofolliculitis	1	0
Trichodynia	5	0
Trichorrhexis	1	0
Pruritus NEC		
Itching scar	4	0
Pruritus	6576	0
Pruritus allergic	1	0
Senile pruritus	1	0
Psoriatic conditions		
Guttate psoriasis	16	0
Psoriasis	136	0
Pustular psoriasis	1	0
Purpura and related conditions		
Ecchymosis	4	0
Henoch-Schonlein purpura	10	0
Petechiae	232	0
Purpura	88	0
Pustular conditions		
Rash follicular	4	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	6	0
Rash	6985	0
Rash erythematous	1882	0
Rash macular	589	0
Rash maculo-papular	53	0
Rash morbilliform	38	0
Rash papular	429	0
Rash pruritic	1534	0
Rash rubelliform	1	0
Rash scarlatiniform	2	0
Rash vesicular	62	0
Systemic lupus erythematosus rash	6	0
Rosaceas		
Erythematotelangiectatic rosacea	1	0
Rosacea	27	0
Scaly conditions		
Pityriasis	6	0
Sebaceous gland disorders		
Seborrhoea	5	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	7	0
Skin mass	29	0
Skin and subcutaneous tissue ulcerations		
Diabetic foot	1	0
Mucocutaneous ulceration	2	0
Pyoderma gangrenosum	2	0
Skin erosion	37	0
Skin ulcer	21	0
Skin cysts and polyps		
Dermal cyst	12	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin dystrophies</i>		
Skin wrinkling	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	14	0
Skin haemorrhage	27	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	1	0
Leukoplakia	1	0
<i>Skin vascular conditions NEC</i>		
Angiodermatitis	1	0
Skin oedema	3	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	7	0
Hypersensitivity vasculitis	3	0
Vasculitic rash	22	1
<i>Skin vasomotor conditions</i>		
Livedo reticularis	43	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	2	0
Telangiectasia	2	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	1944	0
Urticaria chronic	20	0
Urticaria contact	2	0
Urticaria papular	1	0
Urticaria thermal	5	0
Urticularial vasculitis	5	0
Skin disorders SOC TOTAL	41199	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Childhood	1	0
Menarche	2	0
Menopause	14	0
Postmenopause	2	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
<i>Disability issues</i>		
Bedridden	63	0
Breast prosthesis user	1	0
Dependence on oxygen therapy	1	0
Disability	3	0
Hearing aid user	1	0
Hearing disability	1	0
Housebound	2	0
Immobile	37	0
Immobilisation prolonged	3	0
Impaired driving ability	3	0
Impaired work ability	14	0
Loss of personal independence in daily activities	3	0
Sight disability	14	0
Sitting disability	2	0
Walking disability	2	0
<i>Educational issues</i>		
Illiteracy	1	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	5	0
<i>Sexuality issues</i>		
Anal sex	1	0
<i>Social issues NEC</i>		
Blood donor	1	0
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
Impaired quality of life	1	0
Refusal of vaccination	1	0
<i>Tobacco use</i>		
Non-tobacco user	2	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco user	2	0
Social circumstances SOC TOTAL	203	1

Case Series Drug Analysis Print

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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
<i>Cardiac device therapeutic procedures</i>		
Pacemaker generated rhythm	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Pericardial excision	2	0
<i>Contraceptive methods female</i>		
Contraceptive diaphragm	2	0
<i>Corneal and scleral therapeutic procedures</i>		
Corneal transplant	1	0
<i>Dental and gingival therapeutic procedures</i>		
Dental care	1	0
Tooth extraction	1	0
<i>Dietary and nutritional therapies</i>		
Fluid replacement	1	0
Medical diet	4	0
Nothing by mouth order	2	0
<i>External ear therapeutic procedures</i>		
Cerumen removal	1	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>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal resection	1	0
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	26	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	1	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	2	0
Haemofiltration	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Head, neck and oral cavity therapeutic procedures NEC		
Neck lift	1	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	3	0
Hormone therapy	1	0
Immunisations		
COVID-19 immunisation	168	1
Immunisation	77	0
Tuberculosis immunisation	1	0
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Hip surgery	1	0
Joint injection	1	0
Joint stabilisation	1	0
Knee operation	1	0
Large intestine therapeutic procedures		
Appendectomy	5	0
Limb therapeutic procedures		
Leg amputation	2	0
Limb immobilisation	24	0
Limb operation	6	0
Limb reattachment surgery	1	0
Toe amputation	4	0
Mastectomies		
Breast conserving surgery	2	0
Muscle therapeutic procedures		
Muscle relaxant therapy	2	0
Nasal therapeutic procedures		
Nasal irrigation	1	0
Nervous system therapeutic procedures NEC		
Central nervous system stimulation	3	0
Orbit and globe therapeutic procedures		
Eye muscle operation	1	0
Patient positioning		
Prone position	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	3	0
Psychiatric therapies		
Antidepressant therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	1	0
Skin lesion excisions		
Tattoo excision	1	0
Small intestine therapeutic procedures		
Ileostomy	2	0
Spine and spinal cord therapeutic procedures		
Spinal operation	1	0
Testicular and scrotal therapeutic procedures		
Testes exploration	1	0
Therapeutic procedures NEC		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Anaphylaxis treatment	3	0
Antiallergic therapy	1	0
Bed rest	19	0
Catheter management	2	0
Catheter placement	1	0
Fatigue management	1	0
Heat therapy	1	0
Hospitalisation	20	0
Immobilisation bandage	1	0
Injection	34	0
Interchange of vaccine products	1	0
Localised alternating hot and cold therapy	5	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	1	0
Physical fitness training	1	0
Product used for unknown indication	1	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
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	1	0
Hysterectomy	1	0
Vascular therapeutic procedures NEC		
Thrombectomy	2	0
Venous therapeutic procedures		
Phlebotomy	1	0
Surgical & medical procedures SOC TOTAL	515	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	9	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
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 stenosis	2	0
<i>Arterial infections and inflammations</i>		
Arteritis	4	0
Giant cell arteritis	42	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	17	0
Labile blood pressure	2	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	5	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	86	1
Distributive shock	2	0
Hypoperfusion	2	0
Neurogenic shock	10	0
Peripheral circulatory failure	3	0
Shock	42	0
Shock symptom	5	0
<i>Haemorrhages NEC</i>		
Bloody discharge	8	0
Haematoma	80	0
Haemorrhage	528	2
Internal haemorrhage	21	0
Venous haemorrhage	5	0
<i>Lymphangiopathies</i>		
Lymphorrhoea	1	0
<i>Lymphoedemas</i>		
Lymphoedema	51	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	21	1
Embolism	234	3
Embolism arterial	3	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Embolism venous	11	1
Microembolism	2	0
Paradoxical embolism	1	0
Thrombophlebitis migrans	1	0
Thrombosis	1054	20
Venous thrombosis	24	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	9	0
Arterial spasm	2	0
Arterial stenosis	1	0
Arteriosclerosis	3	0
Infarction	7	0
Ischaemia	8	0
Peripheral venous disease	4	0
Vascular compression	1	0
Vasospasm	7	0
<i>Non-site specific vascular disorders NEC</i>		
Angiopathy	2	0
Arterial rupture	1	0
Capillary fragility	8	0
Collateral circulation	1	0
Haemodynamic instability	2	0
Hyperaemia	1	0
Neovascularisation	1	0
Superficial vein prominence	3	0
Vascular pain	83	0
Vascular rupture	1	0
Vascular wall discolouration	1	0
Vasodilatation	80	0
Vein collapse	1	0
Vein discolouration	4	0
Vein disorder	12	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	28	0
Deep vein thrombosis	784	7
Femoral artery embolism	2	0
Iliac artery embolism	2	0
Jugular vein thrombosis	18	0
Pelvic venous thrombosis	11	1
Peripheral artery thrombosis	15	0
Peripheral embolism	8	0
Peripheral vein thrombus extension	1	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	1	0
Thrombophlebitis	84	0
Thrombophlebitis superficial	39	0
Venous thrombosis limb	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	92	0
Erythromelalgia	4	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Flushing	630	0
Hot flush	1774	0
Peripheral vascular disorder	3	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	6	0
Peripheral coldness	1119	0
Peripheral ischaemia	26	2
Poor peripheral circulation	38	0
Raynaud's phenomenon	105	0
Phlebitis NEC		
Phlebitis	42	0
Phlebitis superficial	7	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific vascular disorders NEC		
Pallor	363	0
Plethoric face	1	0
Varicose veins NEC		
Bleeding varicose vein	1	0
Spider vein	10	0
Varicophlebitis	3	0
Varicose vein	85	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	3	0
Hypertension	664	0
Labile hypertension	1	0
Systolic hypertension	2	0
Venous hypertension	3	0
White coat hypertension	10	0
Vascular hypotensive disorders		
Capillary leak syndrome	7	0
Hypotension	425	0
Orthostatic hypotension	37	0
Vascular malformations and acquired anomalies		
Arteriovenous fistula	1	0
Vasculitides NEC		
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	93	3
Vena caval embolism and thrombosis		
Vena cava thrombosis	3	1
Vascular disorders SOC TOTAL	9168	50
TOTAL REACTIONS FOR DRUG	676083	806
TOTAL REPORTS	182751	
TOTAL FATAL OUTCOME REPORTS		806