

## COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021

Data Lock Date: 05-Apr-2021 19:00:03

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All UK spontaneous reports received between 04/01/21 and 05/04/21 for  
COVID-19 vaccine Oxford University/AstraZeneca

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemia deficiencies</i></b>		
Anaemia vitamin B12 deficiency	3	0
Iron deficiency anaemia	1	0
Pernicious anaemia	1	0
<b><i>Anaemias NEC</i></b>		
Anaemia	16	0
Normocytic anaemia	1	0
<b><i>Anaemias haemolytic NEC</i></b>		
Haemolytic anaemia	3	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	1	0
<b><i>Bleeding tendencies</i></b>		
Increased tendency to bruise	33	0
Spontaneous haematoma	1	0
<b><i>Coagulation factor deficiencies</i></b>		
Hypofibrinogenaemia	2	0
<b><i>Coagulopathies</i></b>		
Abnormal clotting factor	2	0
Antiphospholipid syndrome	8	0
Coagulopathy	13	0
Disseminated intravascular coagulation	9	0
Hypercoagulation	6	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	7	0
<b><i>Haematological disorders</i></b>		
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Mast cell activation syndrome	5	0
Mastocytosis	1	0
Methaemoglobinaemia	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	2	0
<b><i>Leukocytoses NEC</i></b>		
Leukocytosis	2	0
Lymphocytosis	1	0
Neutrophilia	3	0
<b><i>Leukopenias NEC</i></b>		
Leukopenia	5	0
Lymphopenia	6	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymph node fibrosis	1	0
Lymph node pain	322	0
Lymphadenitis	14	0
Lymphadenopathy	2859	0
Lymphatic disorder	1	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplastic anaemia	1	0
Pancytopenia	7	0
<b><i>Neutropenias</i></b>		
Agranulocytosis	3	0
Autoimmune neutropenia	1	0
Neutropenia	46	0
<b><i>Platelet disorders NEC</i></b>		

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<b>Blood disorders</b> Blood disorders cont'd		
Platelet anisocytosis	1	0
Platelet disorder	2	0
<b><i>Polycythaemia (excl rubra vera)</i></b>		
Stress polycythaemia	2	0
<b><i>Purpuras (excl thrombocytopenic)</i></b>		
Purpura non-thrombocytopenic	2	0
<b><i>Red blood cell abnormal findings NEC</i></b>		
Anisocytosis	1	0
<b><i>Sickle cell trait and disorders</i></b>		
Sickle cell anaemia with crisis	2	0
<b><i>Spleen disorders</i></b>		
Spleen disorder	1	0
Splenic artery thrombosis	1	0
Splenic infarction	4	0
Splenic varices	1	0
Splenic vein thrombosis	5	0
Splenomegaly	3	0
<b><i>Thrombocytopenias</i></b>		
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	3	0
Immune thrombocytopenia	79	1
Thrombocytopenia	173	2
Thrombocytopenic purpura	6	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	3	0
<b><i>White blood cell abnormal findings NEC</i></b>		
White blood cell disorder	1	0
<b>Blood disorders SOC TOTAL</b>	<b>3681</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Aortic valvular disorders</b></i>		
Aortic valve stenosis	1	0
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	10	0
Atrioventricular block complete	2	0
Bundle branch block	1	0
Bundle branch block left	3	0
Long QT syndrome	1	0
Trifascicular block	1	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	3	1
Atrial thrombosis	1	0
Cardiac disorder	22	0
Cardiac ventricular thrombosis	1	1
Cardiovascular disorder	2	0
Cardiovascular insufficiency	5	0
Intracardiac thrombus	1	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	1	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	6	0
Palpitations	2986	0
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	1	1
Heart valve incompetence	1	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	3	0
Congestive cardiomyopathy	5	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	1	0
Coronary artery thrombosis	3	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	19	4
Cardiac failure acute	2	0
Cardiac failure congestive	1	0
Cardiogenic shock	2	1
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	2	0
Acute myocardial infarction	21	3
Angina pectoris	80	0
Angina unstable	8	0
Arteriospasm coronary	2	0
Microvascular coronary artery disease	2	0
Myocardial infarction	108	23
Myocardial ischaemia	12	5
Prinzmetal angina	1	0
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	2	1
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	1	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
<b><i>Myocardial disorders NEC</i></b>		
Cardiomegaly	3	0
Left ventricular dilatation	1	0
Left ventricular dysfunction	4	0
Myocardial rupture	1	0
Right ventricular dysfunction	1	0
<b><i>Noninfectious myocarditis</i></b>		
Myocarditis	11	1
<b><i>Noninfectious pericarditis</i></b>		
Pericarditis	23	0
<b><i>Pericardial disorders NEC</i></b>		
Pericardial effusion	5	0
Pericardial haemorrhage	2	1
<b><i>Rate and rhythm disorders NEC</i></b>		
Arrhythmia	67	0
Bradycardia	39	0
Cardiac flutter	108	0
Extrasystoles	55	0
Heart alternation	2	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	6	0
Tachyarrhythmia	9	0
Tachycardia	882	0
<b><i>Right ventricular failures</i></b>		
Cor pulmonale	1	0
Right ventricular failure	1	1
<b><i>Supraventricular arrhythmias</i></b>		
Arrhythmia supraventricular	9	0
Atrial fibrillation	131	0
Atrial flutter	16	0
Atrial tachycardia	1	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	1	0
Sinus node dysfunction	1	0
Sinus tachycardia	46	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	17	0
<b><i>Ventricular arrhythmias and cardiac arrest</i></b>		
Cardiac arrest	75	18
Pulseless electrical activity	1	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	2	0
Ventricular fibrillation	3	0
Ventricular tachycardia	11	0
<b>Cardiac disorders SOC TOTAL</b>	<b>4867</b>	<b>64</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<b><i>Cardiac disorders congenital NEC</i></b>		
Heart disease congenital	5	0
<b><i>Cardiac septal defects congenital</i></b>		
Hypertrophic cardiomyopathy	4	0
Ventricular septal defect	1	0
<b><i>Central nervous system disorders congenital NEC</i></b>		
Syringomyelia	2	0
<b><i>Cerebellar disorders congenital</i></b>		
Arnold-Chiari malformation	2	0
<b><i>Cerebral disorders congenital</i></b>		
Cerebral palsy	4	0
<b><i>Coagulation disorders congenital</i></b>		
Haemophilia	2	0
Protein S deficiency	1	0
<b><i>Connective tissue disorders congenital</i></b>		
Ehlers-Danlos syndrome	4	0
<b><i>Great vessel disorders congenital</i></b>		
Transposition of the great vessels	2	0
<b><i>Haematological disorders congenital NEC</i></b>		
Neonatal alloimmune thrombocytopenia	1	0
<b><i>Immune system abnormalities congenital</i></b>		
Combined immunodeficiency	1	0
<b><i>Inborn errors of porphyrin metabolism</i></b>		
Porphyria	1	0
Porphyria acute	1	0
<b><i>Lymphatic system disorders congenital</i></b>		
Cystic lymphangioma	1	0
<b><i>Lysosomal storage disorders</i></b>		
Mucopolysaccharidosis	1	0
<b><i>Male reproductive tract disorders congenital</i></b>		
Hydrocele	1	0
<b><i>Musculoskeletal and connective tissue disorders of limbs congenital</i></b>		
Limb reduction defect	1	0
Polydactyly	1	0
<b><i>Musculoskeletal disorders congenital NEC</i></b>		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	2	0
<b><i>Neurological disorders congenital NEC</i></b>		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
<b><i>Non-site specific muscle disorders congenital</i></b>		
Muscular dystrophy	1	0
<b><i>Pancreatic disorders congenital</i></b>		
Hereditary pancreatitis	1	0
<b><i>Peripheral nervous system disorders congenital NEC</i></b>		
Paroxysmal extreme pain disorder	8	0
<b><i>Pulmonary and bronchial disorders congenital</i></b>		
Cystic fibrosis	4	0
<b><i>Vascular anomalies congenital NEC</i></b>		
Klippel-Trenaunay syndrome	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>57</b>	<b>0</b>

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<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	11	0
Ear discomfort	38	0
Ear disorder	4	0
Ear haemorrhage	4	0
Ear pain	1216	0
Ear pruritus	1	0
Ear swelling	39	0
Otorrhoea	2	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube dysfunction	1	0
<i><b>External ear disorders NEC</b></i>		
Excessive cerumen production	9	0
External ear pain	7	0
Red ear syndrome	5	0
<i><b>Hearing disorders NEC</b></i>		
Auditory disorder	1	0
<i><b>Hearing losses</b></i>		
Deafness	119	0
Deafness bilateral	1	0
Deafness neurosensory	2	0
Deafness transitory	2	0
Deafness unilateral	16	0
Hypoacusis	84	0
Sudden hearing loss	22	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	53	0
<i><b>Inner ear disorders NEC</b></i>		
Inner ear disorder	3	0
Meniere's disease	12	0
Vestibular disorder	2	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	2	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	60	0
Phobic postural vertigo	1	0
Tinnitus	1250	0
Vertigo	838	0
Vertigo labyrinthine	5	0
Vertigo positional	43	0
<i><b>Middle ear disorders NEC</b></i>		
Middle ear effusion	2	0
<i><b>Tympanic membrane disorders (excl infections)</b></i>		
Tympanic membrane perforation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>3856</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	4	0
Thyroiditis chronic	1	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	4	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenal insufficiency	10	0
Adrenocortical insufficiency acute	24	0
Glucocorticoid deficiency	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
Adrenal haemorrhage	3	0
Adrenal mass	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
Ovulation delayed	3	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	3	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
Thyroid disorder	3	0
Thyroid mass	1	0
Thyroid pain	6	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	5	0
Thyrotoxic crisis	2	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	17	0
<b>Endocrine disorders SOC TOTAL</b>	<b>96</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	2	0
<i><b>Cataract conditions</b></i>		
Cataract	6	0
Cataract cortical	2	0
Cataract subcapsular	2	0
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Vitreous haemorrhage	2	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Chorioretinopathy	1	0
Vitreous detachment	11	0
Vitreous floaters	55	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	9	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	36	0
<i><b>Conjunctival infections, irritations and inflammations</b></i>		
Conjunctival hyperaemia	1	0
<i><b>Corneal infections, oedemas and inflammations</b></i>		
Keratitis	2	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	38	0
Excessive eye blinking	1	0
Eyelid ptosis	19	0
<i><b>Glaucomas (excl congenital)</b></i>		
Angle closure glaucoma	1	0
Glaucoma	3	0
<i><b>Iris and ciliary body structural change, deposit and degeneration</b></i>		
Eye colour change	5	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Autoimmune uveitis	1	0
Iridocyclitis	6	0
Iritis	4	0
Uveitis	14	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	154	0
Lacrimation increased	123	0
<i><b>Lens structural change, deposit and degeneration (excl cataracts)</b></i>		
Anterior capsule contraction	1	0
<i><b>Lid bleeding and vascular disorders</b></i>		
Eyelid bleeding	1	0
Eyelid haematoma	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	5	0
Erythema of eyelid	3	0
Eyelid cyst	2	0
Eyelid margin crusting	1	0
Eyelid oedema	7	0
Eyelid rash	3	0
Swelling of eyelid	52	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Eyelid skin dryness	1	0
Eyelid thickening	1	0

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<b>Eye disorders</b> Eye disorders cont'd		
Growth of eyelashes	5	0
Lagophthalmos	1	0
<b>Ocular bleeding and vascular disorders NEC</b>		
Eye haemorrhage	21	0
Ocular vascular disorder	1	0
<b>Ocular disorders NEC</b>		
Dark circles under eyes	3	0
Eye disorder	7	0
Eye oedema	6	0
Eye pain	2117	0
Eye swelling	308	0
Eye symptom	3	0
Eye ulcer	4	0
Eyelid disorder	2	0
Eyelid pain	10	0
Eyelids pruritus	2	0
Ocular discomfort	26	0
Periorbital oedema	9	0
Periorbital pain	3	0
Periorbital swelling	50	0
<b>Ocular infections, inflammations and associated manifestations</b>		
Eye allergy	11	0
Eye discharge	12	0
Eye inflammation	15	0
Eye irritation	130	0
Eye pruritus	165	0
Limbal swelling	3	0
Ocular hyperaemia	196	0
<b>Ocular nerve and muscle disorders</b>		
Extraocular muscle paresis	5	0
Eye movement disorder	21	0
Gaze palsy	2	0
Ocular myasthenia	1	0
Strabismus	2	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	17	0
Asthenopia	189	0
Eyelid sensory disorder	2	0
Foreign body sensation in eyes	20	0
Hypoaesthesia eye	11	0
Photophobia	637	0
<b>Optic disc abnormalities NEC</b>		
Papilloedema	1	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic ischaemic neuropathy	1	0
<b>Orbital structural change, deposit and degeneration</b>		
Lid sulcus deepened	1	0
<b>Pupil disorders</b>		
Miosis	4	0
Mydriasis	15	0
Pupil fixed	4	0
Pupils unequal	4	0
<b>Refractive and accommodative disorders</b>		

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<b>Eye disorders</b> Eye disorders cont'd		
Altered visual depth perception	2	0
Hypermetropia	1	0
<b><i>Retinal bleeding and vascular disorders (excl retinopathy)</i></b>		
Retinal aneurysm	1	0
Retinal artery embolism	1	0
Retinal artery occlusion	3	0
Retinal haemorrhage	3	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	9	0
Retinal vein thrombosis	1	0
Retinal vein varices	1	0
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Macular degeneration	1	0
Macular detachment	1	0
Macular hole	1	0
Neovascular age-related macular degeneration	4	0
Retinal detachment	2	0
Retinal drusen	1	0
Retinal tear	3	0
Retinal toxicity	1	0
Vitreoretinal traction syndrome	1	0
<b><i>Retinal, choroid and vitreous infections and inflammations</i></b>		
Macular oedema	2	0
<b><i>Retinopathies NEC</i></b>		
Acute macular outer retinopathy	3	0
Retinal exudates	4	0
Retinopathy	2	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	5	0
Scleritis	2	0
<b><i>Scleral structural change, deposit and degeneration</i></b>		
Scleral discolouration	1	0
<b><i>Structural change, deposit and degeneration of eye NEC</i></b>		
Deposit eye	1	0
Endocrine ophthalmopathy	2	0
Exophthalmos	2	0
<b><i>Visual colour distortions</i></b>		
Chloropsia	1	0
Chromatopsia	1	0
Xanthopsia	5	0
<b><i>Visual disorders NEC</i></b>		
Diplopia	135	0
Halo vision	7	0
Metamorphopsia	14	0
Photopsia	150	0
Scintillating scotoma	1	0
Vision blurred	995	0
Visual brightness	4	0
Visual snow syndrome	1	0
<b><i>Visual impairment and blindness (excl colour blindness)</i></b>		
Amaurosis fugax	3	0
Blindness	88	0
Blindness transient	5	0

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<b>Eye disorders</b> Eye disorders cont'd		
Blindness unilateral	4	0
Night blindness	3	0
Sudden visual loss	3	0
Visual acuity reduced	8	0
Visual impairment	261	0
<b>Visual pathway disorders</b>		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>6375</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	13	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	1
Pancreatitis	19	1
Pancreatitis acute	5	0
Pancreatitis chronic	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	1	0
<i>Anal and rectal pains</i>		
Proctalgia	12	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	3	0
Anal paraesthesia	1	0
Anal pruritus	2	0
Anorectal discomfort	4	0
Rectal discharge	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	7	0
Tongue cyst	1	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	19	0
Colitis ischaemic	2	1
Colitis microscopic	1	0
Colitis ulcerative	36	0
Crohn's disease	42	0
Inflammatory bowel disease	2	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
Teething	14	0
Tooth disorder	1	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	8	0
Dental paraesthesia	11	0
Hyperaesthesia teeth	29	0
Hypoaesthesia teeth	2	0
Toothache	189	0
<i>Dental pulp disorders</i>		
Dental pulp disorder	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	3	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	5	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	5678	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Diarrhoea haemorrhagic	12	0
<b><i>Diverticula</i></b>		
Diverticulum	4	0
<b><i>Duodenal and small intestinal stenosis and obstruction</i></b>		
Small intestinal obstruction	1	0
<b><i>Duodenal ulcers and perforation</i></b>		
Duodenal ulcer	1	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	493	0
Epigastric discomfort	10	0
Eructation	56	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	9	0
Faecaloma	3	0
Faeces discoloured	29	0
Faeces hard	3	0
Faeces pale	4	0
Faeces soft	10	0
Mucous stools	6	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	232	0
Flatulence	259	0
<b><i>Gastric and oesophageal haemorrhages</i></b>		
Gastric haemorrhage	3	0
<b><i>Gastric ulcers and perforation</i></b>		
Gastric ulcer	4	0
Gastric ulcer perforation	1	0
<b><i>Gastritis (excl infective)</i></b>		
Chronic gastritis	2	0
Gastritis	41	0
Reflux gastritis	9	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	1	0
Abdominal pain	2723	0
Abdominal pain lower	129	0
Abdominal pain upper	3079	0
Abdominal rigidity	28	0
Abdominal tenderness	11	0
Gastrointestinal pain	190	0
Oesophageal pain	4	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	221	0
Duodenogastric reflux	2	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	113	0
Impaired gastric emptying	2	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Food poisoning	4	0
Functional gastrointestinal disorder	7	0
Gastric disorder	5	0
Gastrointestinal disorder	16	0

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gastrointestinal oedema	1	0
Neurogenic bowel	1	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Bowel movement irregularity	2	0
Change of bowel habit	7	0
Dyschezia	7	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	2	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Appendicitis noninfective	1	0
Gastrointestinal tract irritation	3	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Hyperchlorhydria	2	0
<b><i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i></b>		
Gastrointestinal necrosis	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	973	0
Abdominal symptom	4	0
Acute abdomen	9	0
Anal incontinence	23	0
Breath odour	15	0
Dysphagia	106	1
Intestinal congestion	1	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Cardiospasm	1	1
Defaecation urgency	7	0
Frequent bowel movements	25	0
Irritable bowel syndrome	51	0
Oesophageal spasm	4	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	3	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	2	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	4	0
Mesenteric artery thrombosis	1	0
Mesenteric vein thrombosis	4	0
Mesenteric venous occlusion	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	2	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	16	0
Gingival discomfort	3	0
Gingival disorder	10	0
Gingival hypertrophy	1	0
Gingival oedema	2	0
Gingival pain	133	0
Gingival pruritus	1	0
Gingival swelling	26	0
Gingival ulceration	3	0
Noninfective gingivitis	14	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	51	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	17	0
Haemorrhoids thrombosed	4	0
<b><i>Inguinal hernias</i></b>		
Inguinal hernia	3	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	13	0
Intestinal haemorrhage	1	0
Mesenteric haemorrhage	1	0
Rectal haemorrhage	33	0
Small intestinal haemorrhage	16	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	1	0
<b><i>Large intestinal stenosis and obstruction</i></b>		
Large intestinal stenosis	1	0
<b><i>Malabsorption syndromes</i></b>		
Coeliac disease	7	0
Steatorrhoea	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Acetonaemic vomiting	1	0
Discoloured vomit	12	0
Faecal vomiting	2	0
Infantile vomiting	1	0
Nausea	23416	0
Regurgitation	1	0
Retching	175	0
Vomiting	7826	2
Vomiting projectile	103	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	10	0
Haematemesis	37	0
Haematochezia	37	0
Melaena	3	0
Upper gastrointestinal haemorrhage	1	0
<b><i>Oesophageal stenosis and obstruction</i></b>		
Oesophageal obstruction	1	0
<b><i>Oesophagitis (excl infective)</i></b>		
Eosinophilic oesophagitis	2	0
Oesophagitis	7	0
<b><i>Oral dryness and saliva altered</i></b>		
Aptyalism	3	0
Dry mouth	794	0
Lip dry	40	0
Saliva altered	3	0
Saliva discolouration	1	0
Salivary hypersecretion	40	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Angina bullosa haemorrhagica	1	0
Chapped lips	8	0
Cheilitis	19	0
Chronic cheek biting	1	0
Enlarged uvula	5	0



## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Leukoplakia oral	2	0
Lip blister	21	0
Lip disorder	1	0
Oral disorder	8	0
Oral lichen planus	3	0
Uvulitis	4	0
<b>Oral soft tissue haemorrhages</b>		
Lip haemorrhage	2	0
Mouth haemorrhage	19	0
Oral blood blister	24	0
<b>Oral soft tissue infections</b>		
Angular cheilitis	4	0
<b>Oral soft tissue signs and symptoms</b>		
Anaesthesia oral	6	0
Burning mouth syndrome	5	0
Coating in mouth	3	0
Hypoaesthesia oral	382	0
Lip discolouration	1	0
Lip erythema	4	0
Lip exfoliation	7	0
Lip pain	41	0
Lip pruritus	11	0
Odynophagia	20	0
Oral discomfort	49	0
Oral mucosal blistering	17	0
Oral mucosal eruption	13	0
Oral mucosal erythema	2	0
Oral mucosal exfoliation	7	0
Oral mucosal roughening	2	0
Oral pain	215	0
Oral pruritus	13	0
Paraesthesia oral	517	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	5	0
Lip swelling	556	0
Mouth swelling	74	0
Oedema mouth	1	0
Palatal swelling	10	0
<b>Pancreatic disorders NEC</b>		
Pancreatic mass	1	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland calculus	1	0
Salivary gland pain	4	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	7	0
Salivary gland enlargement	4	0
<b>Salivary gland infections and inflammations</b>		
Noninfective sialoadenitis	2	0
<b>Stomatitis and ulceration</b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Apthous ulcer	42	0
Lip ulceration	11	0
Mouth ulceration	419	0
Stomatitis	53	0
<b>Tongue disorders</b>		
Glossitis	12	0
Plicated tongue	3	0
Tongue disorder	19	0
Tongue geographic	2	0
Tongue haemorrhage	1	0
Tongue ulceration	22	0
Trichoglossia	3	0
<b>Tongue signs and symptoms</b>		
Glossodynia	155	0
Scalloped tongue	3	0
Stiff tongue	2	0
Swollen tongue	345	0
Tongue blistering	16	0
Tongue coated	24	0
Tongue discolouration	13	0
Tongue discomfort	30	0
Tongue dry	15	0
Tongue eruption	4	0
Tongue exfoliation	1	0
Tongue movement disturbance	5	0
Tongue oedema	11	0
Tongue pruritus	1	0
Tongue rough	1	0
Tongue spasm	3	0
<b>Tooth missing</b>		
Tooth loss	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>51326</b>	<b>7</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	10	0
Administration site coldness	1	0
Administration site erythema	4	0
Administration site induration	1	0
Administration site mass	1	0
Administration site pain	33	0
Administration site rash	2	0
Administration site reaction	4	0
Administration site urticaria	1	0
Puncture site bruise	38	0
Puncture site haemorrhage	1	0
Puncture site pain	14	0
Puncture site reaction	3	0
Puncture site swelling	1	0
<b><i>Adverse effect absent</i></b>		
No adverse event	12	0
<b><i>Application and instillation site reactions</i></b>		
Application site bruise	15	0
Application site burn	2	0
Application site discolouration	1	0
Application site erythema	19	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	26	0
Application site pruritus	10	0
Application site swelling	4	0
Application site vesicles	3	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	11	0
<b><i>Asthenic conditions</i></b>		
Asthenia	2916	3
Chronic fatigue syndrome	56	0
Decreased activity	3	0
Fatigue	32264	0
Malaise	8183	3
Sluggishness	14	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	8	0
Hyperthermia malignant	1	0
Hypothermia	37	0
Temperature regulation disorder	10	0
<b><i>Complications associated with device NEC</i></b>		
Injury associated with device	2	0
Medical device site joint pain	1	0

## Case Series Drug Analysis Print

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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Phantom shocks	3	0
<b>Death and sudden death</b>		
Brain death	4	1
Death	187	187
Drowning	1	0
Sudden death	20	0
<b>Febrile disorders</b>		
Hyperpyrexia	33	0
Masked fever	1	0
PFAPA syndrome	1	0
Pyrexia	40183	0
<b>Feelings and sensations NEC</b>		
Chills	32199	0
Early satiety	1	0
Feeling abnormal	1651	0
Feeling cold	3718	0
Feeling drunk	76	0
Feeling hot	1529	0
Feeling jittery	24	0
Feeling of body temperature change	688	0
Hangover	102	0
Hunger	41	0
Sensation of blood flow	7	0
Sensation of foreign body	24	0
Temperature intolerance	41	0
Thirst	888	0
Thirst decreased	7	0
<b>Fibrosis NEC</b>		
Fibrosis	2	0
<b>Gait disturbances</b>		
Decreased gait velocity	2	0
Gait disturbance	185	0
Gait inability	105	0
Loss of control of legs	26	0
<b>General signs and symptoms NEC</b>		
Apparent death	1	0
Chronic disease	1	0
Condition aggravated	109	0
Crepitations	3	0
Crying	159	0
Developmental delay	2	0
Discharge	3	0
Energy increased	13	0
Exercise tolerance decreased	12	0
Foaming at mouth	3	0
General physical health deterioration	10	1
General symptom	8	0
Glassy eyes	3	0
High-pitched crying	2	0
Ill-defined disorder	2	0
Illness	3383	0
Induration	11	0
Influenza like illness	6752	1

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Irritability postvaccinal	2	0
Local reaction	126	0
Moaning	6	0
Multiple organ dysfunction syndrome	5	0
Nonspecific reaction	3	0
Organ failure	1	0
Peripheral swelling	3377	0
Pre-existing condition improved	3	0
Screaming	11	0
Secretion discharge	16	0
Stenosis	1	0
Swelling	1572	0
Swelling face	554	0
Symptom recurrence	1	0
Tissue discolouration	1	0
Tissue infiltration	1	0
Unevaluable event	2	0
<b>Hernias NEC</b>		
Hernia	1	0
<b>Implant and catheter site reactions</b>		
Catheter site urticaria	1	0
Implant site coldness	1	0
Implant site discharge	1	0
Implant site discolouration	3	0
Implant site hypoaesthesia	1	0
Implant site pain	3	0
Implant site rash	1	0
Implant site swelling	2	0
Implant site warmth	6	0
<b>Inflammations</b>		
Inflammation	352	0
Systemic inflammatory response syndrome	1	0
<b>Infusion site reactions</b>		
Infusion site bruising	1	0
Infusion site erythema	1	0
Infusion site mass	1	0
Infusion site nodule	1	0
Infusion site pain	6	0
Infusion site urticaria	1	0
Infusion site warmth	4	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	23	0
Injection site atrophy	4	0
Injection site bruising	75	0
Injection site coldness	3	0
Injection site cyst	1	0
Injection site discolouration	4	0
Injection site discomfort	9	0
Injection site dryness	1	0
Injection site erythema	418	0
Injection site exfoliation	1	0
Injection site extravasation	1	0
Injection site haematoma	2	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site haemorrhage	3	0
Injection site hypersensitivity	4	0
Injection site hypoaesthesia	9	0
Injection site indentation	7	0
Injection site induration	3	0
Injection site inflammation	45	0
Injection site injury	1	0
Injection site irritation	2	0
Injection site joint discomfort	1	0
Injection site joint erythema	6	0
Injection site joint pain	27	0
Injection site mass	1003	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site nodule	4	0
Injection site oedema	21	0
Injection site pain	3122	0
Injection site papule	3	0
Injection site paraesthesia	14	0
Injection site pruritus	211	0
Injection site rash	207	0
Injection site reaction	79	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	162	0
Injection site ulcer	1	0
Injection site urticaria	28	0
Injection site vesicles	7	0
Injection site warmth	260	0
<b>Interactions</b>		
Drug interaction	16	0
Inhibitory drug interaction	5	0
<b>Mass conditions NEC</b>		
Cyst	8	0
Mass	43	0
Nodule	7	0
<b>Mucosal findings abnormal</b>		
Mucosal disorder	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	2	0
Mucosal inflammation	2	0
Mucosal pain	2	0
Mucosal ulceration	1	0
Oedema mucosal	2	0
Polyp	1	0
<b>Necrosis NEC</b>		
Necrosis	2	0
<b>Oedema NEC</b>		
Face oedema	17	0
Localised oedema	5	0
Oedema	25	0
Oedema peripheral	44	0
<b>Pain and discomfort NEC</b>		

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Axillary pain	425	0
Chest discomfort	1201	0
Chest pain	2489	0
Discomfort	225	0
Facial discomfort	6	0
Facial pain	149	0
Hernia pain	1	0
Inflammatory pain	13	0
Non-cardiac chest pain	21	0
Pain	10054	0
Tenderness	1325	0
Visceral pain	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	491	2
Adverse event	4	0
Adverse reaction	17	0
Diet failure	1	0
Drug ineffective	53	0
Drug intolerance	2	0
Immediate post-injection reaction	1	0
Inadequate analgesia	10	0
No reaction on previous exposure to drug	34	0
Remission not achieved	1	0
Therapeutic product effect decreased	1	0
Therapeutic reaction time decreased	1	0
Therapeutic response shortened	1	0
Therapeutic response unexpected	39	0
Therapy non-responder	1	0
Treatment failure	3	0
Vaccine positive rechallenge	1	0
<b>Trophic disorders</b>		
Atrophy	2	0
Calcinosis	1	0
<b>Ulcers NEC</b>		
Ulcer	18	0
Ulcer haemorrhage	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	13	0
Shoulder injury related to vaccine administration	8	0
Vaccination site bruising	77	0
Vaccination site coldness	1	0
Vaccination site cyst	1	0
Vaccination site discharge	1	0
Vaccination site discolouration	7	0
Vaccination site discomfort	23	0
Vaccination site erythema	436	0
Vaccination site extravasation	1	0
Vaccination site granuloma	5	0
Vaccination site haemorrhage	3	0
Vaccination site hyperaesthesia	1	0
Vaccination site hypersensitivity	3	0
Vaccination site hypoaesthesia	12	0
Vaccination site induration	40	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site inflammation	40	0
Vaccination site injury	2	0
Vaccination site irritation	9	0
Vaccination site joint erythema	2	0
Vaccination site joint movement impairment	5	0
Vaccination site joint pain	31	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	2	0
Vaccination site mass	341	0
Vaccination site movement impairment	30	0
Vaccination site oedema	2	0
Vaccination site pain	1250	0
Vaccination site papule	2	0
Vaccination site paraesthesia	8	0
Vaccination site pruritus	68	0
Vaccination site rash	97	0
Vaccination site reaction	17	0
Vaccination site scar	3	0
Vaccination site swelling	303	0
Vaccination site urticaria	7	0
Vaccination site vesicles	6	0
Vaccination site warmth	250	0
<b><i>Vascular complications associated with device</i></b>		
Vascular stent occlusion	1	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	39	0
<b>General disorders SOC TOTAL</b>	<b>167736</b>	<b>2GF</b>



## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021  
 Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	12	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	5	0
Cholelithiasis	5	0
<i><b>Cholestasis and jaundice</b></i>		
Jaundice	19	0
Jaundice cholestatic	4	0
Ocular icterus	1	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	2	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Hepatic failure	1	0
Subacute hepatic failure	1	0
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	2	0
<i><b>Hepatic vascular disorders</b></i>		
Budd-Chiari syndrome	1	1
Hepatic artery thrombosis	1	0
Hepatic vein thrombosis	4	0
Portal vein thrombosis	11	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	42	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Hepatitis	11	0
Hepatitis acute	2	0
Liver injury	7	0
<b>Hepatic disorders SOC TOTAL</b>	<b>137</b>	<b>1</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	10	0
<i>Allergic conditions NEC</i>		
Allergic oedema	14	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	739	0
Infusion related hypersensitivity reaction	3	0
Multiple allergies	8	0
Serum sickness	14	0
Serum sickness-like reaction	11	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	1	0
Allergy to chemicals	5	0
Allergy to vaccine	33	0
Contrast media reaction	1	0
Drug hypersensitivity	42	0
Food allergy	6	0
Reaction to excipient	9	0
Reaction to preservatives	9	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	411	1
Anaphylactic shock	69	0
Anaphylactoid reaction	11	0
Anaphylactoid shock	3	0
<i>Atopic disorders</i>		
Seasonal allergy	25	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	10	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	10	0
Cytokine release syndrome	1	0
Haemophagocytic lymphohistiocytosis	2	0
Immune system disorder	10	0
Immunisation reaction	1	0
Pre-engraftment immune reaction	1	0
Sensitisation	19	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immunosuppression	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Transplant rejection	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>1495</b>	<b>1</b>

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Anal abscess	1	0
Appendicitis	14	0
Diarrhoea infectious	1	0
Diverticulitis	6	0
Dysentery	3	0
Gastroenteritis	20	0
Gastrointestinal infection	3	0
<b><i>Bacterial infections NEC</i></b>		
Administration site cellulitis	1	0
Arthritis bacterial	2	0
Bacterial infection	14	1
Cellulitis	318	1
Endocarditis bacterial	1	0
Injection site cellulitis	6	0
Perichondritis	1	0
Pneumonia bacterial	2	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	13	0
<b><i>Bone and joint infections</i></b>		
Arthritis infective	2	0
Intervertebral discitis	1	0
Osteomyelitis	1	0
<b><i>Bordetella infections</i></b>		
Pertussis	1	0
<b><i>Borrelial infections</i></b>		
Erythema migrans	1	0
Lyme disease	4	0
<b><i>Breast infections</i></b>		
Mastitis	9	0
<b><i>Candida infections</i></b>		
Anal candidiasis	1	0
Balanitis candida	1	0
Candida infection	28	0
Oral candidiasis	17	0
Skin candida	1	0
Vulvovaginal candidiasis	18	0
<b><i>Central nervous system and spinal infections</i></b>		
Cavernous sinus thrombosis	2	0
Encephalitis	8	0
Extradural abscess	1	0
Meningitis	11	0
Myelitis	4	0
<b><i>Chlamydial infections</i></b>		
Chlamydial infection	1	0
<b><i>Clostridia infections</i></b>		
Clostridium difficile colitis	1	0
Tetanus	1	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	3	0
COVID-19	270	16
COVID-19 pneumonia	15	6
Coronavirus infection	3	0

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Severe acute respiratory syndrome	4	0
Suspected COVID-19	26	0
<b><i>Corynebacteria infections</i></b>		
Diphtheria	1	0
<b><i>Coxiella infections</i></b>		
Q fever	86	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	1	0
Gingival abscess	3	0
Gingivitis	16	0
Lip infection	1	0
Oral pustule	2	0
Parotitis	9	0
Pericoronitis	1	0
Periodontitis	1	0
Tongue abscess	3	0
Tooth abscess	4	0
Tooth infection	5	0
<b><i>Ear infections</i></b>		
Ear infection	27	0
Labyrinthitis	62	0
Mastoiditis	2	0
Otitis externa	1	0
Otitis media	4	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	1	0
Trombidiasis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	33	0
<b><i>Escherichia infections</i></b>		
Escherichia sepsis	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	41	0
Eye infection	10	0
Eyelid boil	1	0
Eyelid infection	3	0
Hordeolum	14	0
Keratouveitis	1	0
<b><i>Female reproductive tract infections</i></b>		
Endometritis	1	0
Vaginal abscess	1	0
Vaginal infection	1	0
<b><i>Flaviviral infections</i></b>		
Yellow fever	1	0
Yellow fever vaccine-associated neurotropic disease	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	5	0
Fungal skin infection	3	0
Severe asthma with fungal sensitisation	2	0
Tonsillitis fungal	1	0
Vulvovaginal mycotic infection	3	0
<b><i>Hepatitis viral infections</i></b>		

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Hepatitis E	1	0
<b>Hepatobiliary and spleen infections</b>		
Biliary sepsis	2	1
<b>Herpes viral infections</b>		
Eczema herpeticum	1	0
Genital herpes	27	0
Genital herpes simplex	1	0
Herpes ophthalmic	11	0
Herpes simplex	17	0
Herpes simplex reactivation	2	0
Herpes virus infection	7	0
Herpes zoster	425	0
Herpes zoster oticus	2	0
Nasal herpes	7	0
Ophthalmic herpes zoster	2	0
Oral herpes	399	0
Varicella	10	0
<b>Infections NEC</b>		
Abscess	14	0
Abscess limb	5	0
Catheter site infection	1	0
Coinfection	1	0
Genital abscess	1	0
Infected bite	1	0
Infected cyst	1	0
Infection	224	3
Infection in an immunocompromised host	3	0
Injection site abscess	1	0
Injection site infection	9	0
Localised infection	61	0
Lymph gland infection	2	0
Omphalitis	1	0
Pathogen resistance	1	0
Respiratory tract infection	4	0
Toxic shock syndrome	1	0
Vaccination site abscess	2	0
Vaccination site infection	16	0
Vestibulitis	1	0
<b>Infectious transmissions</b>		
Secondary transmission	4	0
<b>Influenza viral infections</b>		
H2N2 influenza	1	0
Influenza	4671	0
<b>Lower respiratory tract and lung infections</b>		
Bronchitis	9	0
Infectious pleural effusion	1	0
Infective exacerbation of bronchiectasis	1	0
Lower respiratory tract infection	100	3
Pneumonia	86	15
<b>Male reproductive tract infections</b>		
Epididymitis	1	0
Orchitis	1	0
<b>Mumps viral infections</b>		

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Mumps	3	0
<b>Muscle and soft tissue infections</b>		
Muscle abscess	1	0
Soft tissue infection	3	0
<b>Phleboviral infections</b>		
Severe fever with thrombocytopenia syndrome	5	0
<b>Plasmodia infections</b>		
Malaria	1	0
<b>Pneumocystis infections</b>		
Pneumocystis jirovecii pneumonia	1	0
<b>Retroviral infections</b>		
Acquired immunodeficiency syndrome	1	0
HIV-associated neurocognitive disorder	1	0
<b>Rubeola viral infections</b>		
Measles	1	0
<b>Salmonella infections</b>		
Typhoid fever	1	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Neutropenic sepsis	4	0
Sepsis	44	4
Sepsis syndrome	1	0
Septic rash	3	0
Septic shock	1	0
Urosepsis	5	1
Viraemia	3	0
<b>Skin structures and soft tissue infections</b>		
Carbuncle	1	0
Dermatitis infected	6	0
Folliculitis	3	0
Infected dermal cyst	2	0
Pustule	5	0
Rash pustular	10	0
Skin infection	44	0
Subcutaneous abscess	7	0
Vaccination site pustule	3	0
<b>Staphylococcal infections</b>		
Furuncle	20	0
Staphylococcal scalded skin syndrome	1	0
Staphylococcal sepsis	3	1
Toxic shock syndrome staphylococcal	1	0
<b>Streptococcal infections</b>		
Cellulitis streptococcal	1	0
Erysipelas	1	0
Pharyngitis streptococcal	3	0
Scarlet fever	1	0
Tonsillitis streptococcal	1	0
<b>Tinea infections</b>		
Body tinea	3	0
Tinea cruris	1	0
Tinea infection	1	0
Tinea pedis	2	0
<b>Trypanosomal infections</b>		
African trypanosomiasis	5	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<i><b>Tuberculous infections</b></i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	3	0
Tuberculosis	3	0
<i><b>Upper respiratory tract infections</b></i>		
Acute sinusitis	2	0
Chronic sinusitis	4	0
Epiglottitis	1	0
Laryngitis	12	0
Nasopharyngitis	1068	0
Pharyngitis	14	0
Rhinitis	23	0
Sinobronchitis	1	0
Sinusitis	150	0
Tonsillitis	41	0
Tracheitis	1	0
Upper respiratory tract infection	2	0
<i><b>Urinary tract infections</b></i>		
Cystitis	47	0
Kidney infection	23	0
Pyelonephritis	1	0
Urinary tract infection	89	0
<i><b>Vascular infections</b></i>		
Infected lymphocele	1	0
Lymphangitis	4	0
<i><b>Viral infections NEC</b></i>		
Arthritis viral	1	0
Bronchitis viral	1	0
Encephalitis viral	3	0
Gastroenteritis viral	46	0
Meningitis viral	7	0
Pneumonia viral	5	1
Post viral fatigue syndrome	52	0
Sweating fever	549	0
Vestibular neuronitis	9	0
Viral diarrhoea	3	0
Viral infection	25	0
Viral labyrinthitis	2	0
Viral myocarditis	1	0
Viral pharyngitis	17	0
Viral rash	39	0
Viral sepsis	1	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
<b>Infections SOC TOTAL</b>	<b>9794</b>	<b>53</b>

## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021  
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Abdomen crushing	2	0
Colon injury	1	0
Lip injury	1	0
Oral contusion	3	0
Palate injury	1	0
Splenic rupture	1	0
Tongue injury	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	8	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Anaesthetic complication	1	0
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	4	0
Sedation complication	2	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotrauma	1	0
Hypobarism	2	0
<b><i>Bone and joint injuries NEC</i></b>		
Bursa injury	1	0
Joint injury	3	0
<b><i>Cardiovascular injuries</i></b>		
Heart injury	2	0
Vascular injury	2	0
<b><i>Cerebral injuries NEC</i></b>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	1	0
Cranio-cerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	3	0
Subdural haemorrhage	1	0
<b><i>Chemical injuries</i></b>		
Chemical burn of oral cavity	1	0
Chemical burn of skin	2	0
Chemical phlebitis	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	6	0
Traumatic lung injury	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	34	0
<b><i>Cranial nerve injuries</i></b>		
Optic nerve injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	3	0
Exposure via breast milk	36	0
Foetal exposure during pregnancy	24	0
Maternal exposure during breast feeding	562	0
Maternal exposure during pregnancy	125	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	2	0
Paternal exposure during pregnancy	5	0
<b><i>Exposures to agents or circumstances NEC</i></b>		



## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Exposure to SARS-CoV-2	2	0
Exposure to toxic agent	1	0
<b>Eye injuries NEC</b>		
Eye contusion	27	0
Eye injury	6	0
Foreign body in eye	1	0
Periorbital haematoma	1	0
Periorbital haemorrhage	1	0
Retinal injury	1	0
Superficial injury of eye	1	0
<b>Fractures and dislocations NEC</b>		
Joint dislocation	3	0
Stress fracture	2	0
<b>Gastrointestinal and hepatobiliary procedural complications</b>		
Procedural nausea	21	0
Procedural vomiting	6	0
<b>Heat injuries (excl thermal burns)</b>		
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	10	0
Heat stroke	5	0
<b>Limb fractures and dislocations</b>		
Ankle fracture	2	0
Clavicle fracture	10	0
Lower limb fracture	1	0
Patella fracture	1	0
Upper limb fracture	1	0
<b>Medication errors, product use errors and issues NEC</b>		
Device use issue	1	0
Intercepted medication error	1	0
Medication error	8	0
Product use issue	1	0
Vaccination error	1	0
Wrong drug	2	0
Wrong technique in product usage process	4	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	8	0
Ligament rupture	1	0
Ligament sprain	8	0
Muscle injury	12	0
Muscle rupture	6	0
Muscle strain	13	0
Post-traumatic neck syndrome	2	0
Repetitive strain injury	1	0
Tendon injury	1	0
Tendon rupture	5	0
<b>Nerve injuries NEC</b>		
Nerve injury	33	0
<b>Neurological and psychiatric procedural complications</b>		
Post lumbar puncture syndrome	6	0
Procedural dizziness	22	0
<b>Non-occupational environmental exposures</b>		
Exposure to chemical pollution	1	0

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Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Exposure to extreme temperature	5	0
Exposure to noise	2	0
<b>Non-site specific injuries NEC</b>		
Animal bite	1	0
Arthropod bite	3	0
Arthropod sting	9	0
Bite	1	0
Electric shock	11	0
Fall	128	1
Inflammation of wound	3	0
Injury	2	0
Internal injury	1	0
Nervous system injury	1	0
Post concussion syndrome	2	0
Road traffic accident	1	0
Tissue injury	1	0
Traumatic haematoma	1	0
Traumatic shock	1	0
Wound	2	0
Wound complication	7	0
Wound haemorrhage	5	0
Wound secretion	1	0
<b>Non-site specific procedural complications</b>		
Incision site erythema	1	0
Incision site haemorrhage	1	0
Incision site oedema	1	0
Incision site pain	9	0
Infusion related reaction	18	0
Injection related reaction	515	0
Needle fatigue	1	0
Post procedural complication	29	0
Post procedural contusion	2	0
Procedural hypertension	1	0
Procedural pain	2	0
Procedural site reaction	1	0
Suture related complication	1	0
<b>Occupational exposures</b>		
Occupational exposure to product	1	0
<b>Off label uses</b>		
Off label use	2	0
<b>Overdoses NEC</b>		
Intentional overdose	1	0
Overdose	12	0
<b>Peripheral nerve injuries</b>		
Ulnar nerve injury	1	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	3	0
Chemical poisoning	1	0
Poisoning	3	0
Systemic toxicity	1	0
Toxicity to various agents	4	0
<b>Product administration errors and issues</b>		
Accidental overdose	2	0

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Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Contraindicated product administered	3	0
Duplicate therapy error	2	0
Expired product administered	11	0
Extra dose administered	2	0
Inappropriate schedule of product administration	3	0
Incorrect dose administered	1	0
Incorrect route of product administration	5	0
Intercepted product administration error	1	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	3	0
Product administered to patient of inappropriate age	3	0
Product administration error	5	0
Wrong patient received product	1	0
Wrong product administered	7	0
<b>Product confusion errors and issues</b>		
Product label confusion	1	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	7	0
<b>Product monitoring errors and issues</b>		
Product monitoring error	1	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	3	0
Product prescribing error	1	0
<b>Product storage errors and issues in the product use system</b>		
Product storage error	2	0
<b>Radiation injuries</b>		
Sunburn	18	0
<b>Renal and urinary tract injuries NEC</b>		
Bladder injury	1	0
<b>Reproductive system and breast injuries</b>		
Penile contusion	1	0
<b>Reproductive tract and breast procedural complications</b>		
Postmastectomy lymphoedema syndrome	1	0
<b>Respiratory tract and thoracic cavity procedural complications</b>		
Pulmonary oil microembolism	1	0
<b>Site specific injuries NEC</b>		
Back injury	5	0
Central nervous system injury	1	0
Face injury	1	0
Head injury	8	0
Limb crushing injury	5	0
Limb injury	71	0
Neck crushing	1	0
Neck injury	2	0
<b>Site specific procedural complications NEC</b>		
Axillary web syndrome	1	0
<b>Skin injuries NEC</b>		
Contusion	1050	0
Scar	4	0
Skin abrasion	2	0
Skin injury	5	0
Skin laceration	1	0
Skin wound	3	0

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Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Subcutaneous haematoma	1	0
<b>Spinal cord injuries NEC</b>		
Prevertebral soft tissue swelling of cervical space	1	0
Spinal cord injury sacral	1	0
<b>Spinal fractures and dislocations</b>		
Spinal compression fracture	1	0
Spinal fracture	1	0
<b>Stoma complications</b>		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
<b>Thermal burns</b>		
Airway burns	1	0
Burn of internal organs	4	0
Burn oral cavity	3	0
Burns second degree	3	0
Cold burn	3	0
Thermal burn	31	0
Thermal burns of eye	31	0
<b>Underdoses NEC</b>		
Intentional underdose	1	0
Underdose	2	0
<b>Vaccination related complications</b>		
Adverse event following immunisation	1	0
Vaccination complication	66	0
Vaccination failure	7	0
<b>Injuries SOC TOTAL</b>	<b>3305</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal cortex tests</i></b>		
Blood cortisol	1	0
Cortisol decreased	1	0
Cortisol increased	1	0
<b><i>Adrenal medulla tests</i></b>		
Norepinephrine increased	2	0
<b><i>Auditory function diagnostic procedures</i></b>		
Acoustic stimulation tests	1	0
<b><i>Autoimmunity analyses</i></b>		
Antiphospholipid antibodies positive	1	0
Cold agglutinins positive	1	0
DNA antibody positive	1	0
Rheumatoid factor	1	0
<b><i>Bacteria identification and serology (excl mycobacteria)</i></b>		
Bacterial test	1	0
<b><i>Blood counts NEC</i></b>		
Blood count	2	0
Full blood count	4	0
Full blood count decreased	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Blood gases	1	0
Blood lactic acid	1	0
Blood pH	9	0
Blood pH increased	5	0
Oxygen consumption	1	0
Oxygen saturation	18	0
Oxygen saturation decreased	120	0
<b><i>Blood grouping and cross-matching analyses</i></b>		
Blood group O	1	0
<b><i>Bone marrow and immune tissue imaging procedures</i></b>		
Scan lymph nodes	1	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	16	0
Blood glucose abnormal	9	0
Blood glucose decreased	27	0
Blood glucose fluctuation	19	0
Blood glucose increased	133	0
Glycosylated haemoglobin increased	2	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	10	0
Heart sounds	12	0
Heart sounds abnormal	3	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Cardiac monitoring	1	0
Echocardiogram	1	0
Myocardial strain	2	0
<b><i>Cardiac imaging procedures</i></b>		
Magnetic resonance imaging heart	1	0
<b><i>Cell marker analyses</i></b>		
Carcinoembryonic antigen increased	1	0
<b><i>Central nervous system imaging procedures</i></b>		
Computerised tomogram head	3	0
Magnetic resonance imaging brain	35	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Cerebrospinal fluid tests (excl microbiology)</i></b>		
CSF pressure	2	0
<b><i>Chemistry analyses NEC</i></b>		
Histamine abnormal	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	2	0
<b><i>Cholesterol analyses</i></b>		
Blood cholesterol increased	2	0
Very low density lipoprotein decreased	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time prolonged	12	0
Bleeding time abnormal	1	0
Blood fibrinogen	1	0
Blood fibrinogen abnormal	1	0
Blood fibrinogen decreased	2	0
Blood fibrinogen increased	1	0
Coagulation factor	1	0
Coagulation time	3	0
Coagulation time prolonged	4	0
Coagulation time shortened	2	0
Fibrin D dimer	1	0
Fibrin D dimer increased	7	0
International normalised ratio	1	0
International normalised ratio abnormal	3	0
International normalised ratio decreased	25	0
International normalised ratio increased	43	0
Prothrombin time prolonged	1	0
Thrombin time	1	0
<b><i>ECG investigations</i></b>		
Electrocardiogram	1	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	8	0
Electrocardiogram change	1	0
Electrocardiogram normal	1	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	4	0
<b><i>Faecal analyses NEC</i></b>		
Faecal calprotectin increased	4	0
<b><i>Fertility analyses</i></b>		
Semen volume decreased	1	0
<b><i>Foetal and neonatal diagnostic procedures</i></b>		
Foetal heart rate	1	0
<b><i>Gastrointestinal and abdominal imaging procedures</i></b>		
Computerised tomogram abdomen	2	0
<b><i>Gastrointestinal function diagnostic procedures</i></b>		
Gastric pH decreased	1	0
Gastrointestinal stoma output increased	1	0
Swallow study	1	0
<b><i>Gastrointestinal, pancreatic and APUD hormone analyses</i></b>		
Blood gastrin	1	0

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood gastrin normal	1	0
Blood insulin	4	0
Blood insulin decreased	2	0
Blood insulin increased	2	0
<b>Haematological analyses NEC</b>		
Blood viscosity abnormal	1	0
Blood viscosity increased	1	0
Red blood cell sedimentation rate increased	2	0
<b>Heart rate and pulse investigations</b>		
Brachial pulse decreased	1	0
Heart rate	703	0
Heart rate abnormal	27	0
Heart rate decreased	56	0
Heart rate increased	1314	0
Heart rate irregular	96	0
Heart rate variability increased	1	0
Maximum heart rate	4	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	15	0
Pulse absent	3	0
Pulse waveform abnormal	1	0
Sinus rhythm	3	0
<b>Imaging procedures NEC</b>		
Computerised tomogram	2	0
Scan	1	0
<b>Immunoglobulin analyses</b>		
Blood immunoglobulin E increased	2	0
<b>Immunology analyses NEC</b>		
Antibody test negative	2	0
Immunology test	2	0
Immunology test normal	1	0
Mast cell degranulation present	1	0
<b>Immunology skin tests NEC</b>		
Allergy alert test	2	0
Skin test positive	2	0
<b>Investigations NEC</b>		
Blood test	16	0
Blood test abnormal	13	0
Investigation	1	0
Polymerase chain reaction positive	1	0
<b>Liver function analyses</b>		
Alanine aminotransferase increased	5	0
Aspartate aminotransferase increased	2	0
Bile output	3	0
Blood bilirubin	1	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme increased	1	0
Liver function test	2	0
Liver function test abnormal	12	0
Transaminases increased	5	0
<b>Metabolism tests NEC</b>		

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood ketone body	9	0
Ubiquinone	2	0
<b>Microbiology and serology tests NEC</b>		
Blood culture	2	0
<b>Mineral and electrolyte analyses</b>		
Blood iron	2	0
Blood iron decreased	2	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium decreased	4	0
Blood potassium increased	3	0
Blood sodium	2	0
Blood sodium decreased	2	0
Sweat test	1	0
Urine copper	1	0
<b>Musculoskeletal and soft tissue imaging procedures</b>		
Skull X-ray	1	0
<b>Musculoskeletal and soft tissue tests NEC</b>		
Swollen joint count	1	0
Swollen joint count increased	2	0
Tender joint count	3	0
<b>Mycobacteria identification and serology</b>		
Interferon gamma release assay positive	1	0
<b>Neurologic diagnostic procedures</b>		
Coma scale abnormal	1	0
Lumbar puncture	6	0
<b>Ophthalmic function diagnostic procedures</b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	1	0
Intraocular pressure test	4	0
Visual tracking test	1	0
<b>Physical examination procedures and organ system status</b>		
Body height decreased	1	0
Body surface area	2	0
Body temperature	751	0
Body temperature abnormal	53	0
Body temperature decreased	88	0
Body temperature fluctuation	116	0
Body temperature increased	836	0
Breath sounds abnormal	3	0
Dermatologic examination abnormal	1	0
Grip strength	2	0
Grip strength decreased	19	0
Head lag	9	0
Lymph node palpable	2	0
Male genital examination abnormal	1	0
Menstruation normal	1	0
Muscle strength abnormal	1	0
Neurological examination	1	0
Psoriasis area severity index decreased	1	0
Respiratory rate	9	0
Respiratory rate decreased	14	0
Respiratory rate increased	48	0



## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Skin temperature	132	0
Temperature difference of extremities	3	0
Urological examination	1	0
Weight decreased	78	0
Weight increased	8	0
<b><i>Pituitary analyses anterior</i></b>		
Blood corticotrophin	1	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	4	0
<b><i>Platelet analyses</i></b>		
Platelet count	1	0
Platelet count decreased	71	0
Platelet count increased	2	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein abnormal	2	0
C-reactive protein increased	6	0
<b><i>Red blood cell analyses</i></b>		
Haematocrit	3	0
Haemoglobin	3	0
Haemoglobin decreased	2	0
Mean cell volume abnormal	1	0
Red blood cell count	1	0
<b><i>Renal function analyses</i></b>		
Blood creatine increased	1	0
Blood creatinine abnormal	1	0
Blood creatinine decreased	1	0
Blood creatinine increased	1	0
Blood urea	2	0
Blood urea increased	1	0
<b><i>Reproductive hormone analyses</i></b>		
Human chorionic gonadotropin decreased	1	0
Pregnancy test	2	0
Pregnancy test negative	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume	2	0
Forced expiratory volume decreased	1	0
Forced expiratory volume increased	9	0
Forced expiratory volume normal	1	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	1	0
Pulmonary function test decreased	1	0
Slow vital capacity	1	0
Total lung capacity decreased	2	0
<b><i>Respiratory tract and thoracic histopathology procedures</i></b>		
Sputum abnormal	1	0
<b><i>Respiratory tract and thoracic imaging procedures</i></b>		
Chest X-ray	5	0
Computerised tomogram thorax	2	0
Laryngoscopy	1	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	2	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	1	0
Troponin	1	0
Troponin T	1	0
<b>Therapeutic drug monitoring analyses</b>		
Analgesic drug level	13	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	2	0
Antidepressant drug level decreased	1	0
<b>Thyroid analyses</b>		
Thyroxine	1	0
Thyroxine abnormal	1	0
Tri-iodothyronine decreased	3	0
<b>Tissue enzyme analyses NEC</b>		
Blood lactate dehydrogenase	1	0
Lactate dehydrogenase urine increased	1	0
<b>Toxicology laboratory analyses</b>		
Blood carbon monoxide increased	1	0
Blood heavy metal test	1	0
Blood lead	1	0
<b>Urinalysis NEC</b>		
Blood urine	15	0
Blood urine present	31	0
Cells in urine	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	8	0
Urine analysis normal	1	0
pH urine	8	0
pH urine decreased	1	0
pH urine increased	2	0
<b>Urinary tract function analyses NEC</b>		
Urine output	33	0
Urine output decreased	9	0
Urine output increased	6	0
<b>Vascular auscultatory investigations</b>		
Abdominal bruit	1	0
<b>Vascular imaging procedures NEC</b>		
Venogram	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	1	0
Blood pressure decreased	44	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	159	0
Blood pressure measurement	47	0
Blood pressure normal	1	0
Blood pressure systolic increased	4	0
Capillary nail refill test	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
<b><i>Virus identification and serology</i></b>		
Coronavirus test	24	0
HIV antibody negative	2	0
Hepatitis B core antibody positive	1	0
Herpes virus test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	3	0
SARS-CoV-2 antibody test negative	11	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test	16	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	11	0
SARS-CoV-2 test positive	49	0
Viral test	2	0
<b><i>Vitamin analyses</i></b>		
Blood folate	1	0
Blood folate decreased	1	0
Vitamin B12 decreased	1	0
<b><i>Water and electrolyte analyses NEC</i></b>		
Blood osmolarity	1	0
Volume blood	2	0
<b><i>White blood cell analyses</i></b>		
Eosinophil count increased	1	0
Lymphocyte count	1	0
Lymphocyte count decreased	1	0
Neutrophil count	2	0
Neutrophil count decreased	6	0
Neutrophil toxic granulation present	1	0
White blood cell count	9	0
White blood cell count decreased	8	0
White blood cell count increased	4	0
<b>Investigations SOC TOTAL</b>	<b>5878</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Appetite disorder	26	0
Decreased appetite	4698	0
Diet refusal	2	0
Food craving	10	0
Food refusal	28	0
Hyperphagia	5	0
Hypophagia	18	0
Increased appetite	33	0
Salt craving	2	0
<b><i>Calcium metabolism disorders</i></b>		
Hypocalcaemia	3	0
Tetany	1	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Diabetes mellitus	39	0
Diabetes mellitus inadequate control	22	0
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Type 1 diabetes mellitus	13	0
Type 2 diabetes mellitus	1	0
<b><i>Diabetic complications NEC</i></b>		
Diabetic ketoacidosis	17	2
Diabetic ketosis	4	0
Euglycaemic diabetic ketoacidosis	1	0
<b><i>Disorders of purine metabolism</i></b>		
Gout	48	0
<b><i>Electrolyte imbalance NEC</i></b>		
Electrolyte imbalance	1	0
Hyperosmolar state	1	1
<b><i>Fat soluble vitamin deficiencies and disorders</i></b>		
Vitamin D deficiency	1	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	7	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	11	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Alcohol intolerance	3	0
Food intolerance	7	0
Gluten sensitivity	2	0
Histamine intolerance	2	0
<b><i>General nutritional disorders NEC</i></b>		
Abnormal loss of weight	25	0
Abnormal weight gain	7	0
Cachexia	1	0
Feeding disorder	113	0
Food aversion	43	0
Neonatal insufficient breast milk syndrome	2	0
Overweight	1	0
Poor feeding infant	6	0
Starvation	1	0
Underweight	1	0
<b><i>Hyperglycaemic conditions NEC</i></b>		
Glucose tolerance impaired	1	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
Hyperglycaemia	97	0
Insulin resistance	7	0
Metabolic syndrome	1	0
<b>Hyperlipidaemias NEC</b>		
Hyperlipidaemia	1	0
<b>Hypoglycaemic conditions NEC</b>		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	65	0
Hypoglycaemia unawareness	2	0
Postprandial hypoglycaemia	1	0
<b>Iron deficiencies</b>		
Iron deficiency	3	0
<b>Lipid metabolism and deposit disorders NEC</b>		
Lipoedema	1	0
<b>Magnesium metabolism disorders</b>		
Hypomagnesaemia	1	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Ketoacidosis	1	0
Ketosis	1	0
Lactic acidosis	2	0
Metabolic acidosis	4	0
<b>Mixed acid-base disorders</b>		
Acidosis	1	0
<b>Phosphorus metabolism disorders</b>		
Hypophosphataemia	1	0
<b>Potassium imbalance</b>		
Hyperkalaemia	2	0
Hypokalaemia	2	0
<b>Protein metabolism disorders NEC</b>		
Hypoalbuminaemia	1	0
<b>Sodium imbalance</b>		
Hypernatraemia	2	0
Hyponatraemia	10	0
Hyponatraemic syndrome	1	0
<b>Sugar intolerance (excl glucose intolerance)</b>		
Lactose intolerance	3	0
<b>Total fluid volume decreased</b>		
Dehydration	433	0
Hypovolaemia	1	0
<b>Total fluid volume increased</b>		
Fluid overload	3	0
Fluid retention	33	0
<b>Water soluble vitamin deficiencies</b>		
Folate deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>5891</b>	<b>3</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	173	0
Arthritis enteropathic	1	0
Arthropathy	11	0
Autoimmune arthritis	1	0
Haemarthrosis	1	0
Palindromic rheumatism	2	0
Polyarthritis	5	0
Rheumatic fever	1	0
Sacroiliitis	3	0
<i><b>Bone disorders NEC</b></i>		
Bone loss	1	0
Jaw disorder	3	0
Medial tibial stress syndrome	6	0
Osteitis	5	0
Osteonecrosis of jaw	2	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	681	0
Coccydynia	3	0
Pain in jaw	342	0
Pubic pain	1	0
Spinal pain	145	0
<i><b>Bursal disorders</b></i>		
Bursitis	38	0
<i><b>Cartilage disorders</b></i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	16	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	1	0
Mixed connective tissue disease	1	0
Morphoea	1	0
Polymyalgia rheumatica	30	0
Reynold's syndrome	5	0
Scleroderma	1	0
<i><b>Epiphyseal disorders</b></i>		
Epiphyses premature fusion	1	0
<i><b>Extremity deformities</b></i>		
Finger deformity	1	0
Hand deformity	1	0
Limb deformity	3	0
<i><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	1	0
<i><b>Joint related disorders NEC</b></i>		
Joint laxity	3	0
Joint lock	23	0
Patellofemoral pain syndrome	1	0
Periarthritis	101	0
Rotator cuff syndrome	20	0
Temporomandibular joint syndrome	8	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	14891	0
Jaw clicking	3	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Joint effusion	1	0
Joint noise	14	0
Joint range of motion decreased	1	0
Joint stiffness	233	0
Joint swelling	295	0
Joint vibration	2	0
Joint warmth	16	0
Loose body in joint	1	0
<b>Ligament disorders</b>		
Ligament pain	1	0
<b>Lupus erythematosus (incl subtypes)</b>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	13	0
<b>Metabolic bone disorders</b>		
Osteopenia	1	0
Osteoporosis	5	0
<b>Muscle infections and inflammations</b>		
Myositis	7	0
Polymyositis	1	0
<b>Muscle pains</b>		
Fibromyalgia	153	0
Myalgia	19205	0
Myofascial pain syndrome	10	0
<b>Muscle related signs and symptoms NEC</b>		
Muscle atrophy	3	0
Muscle discomfort	6	0
Muscle disorder	3	0
Muscle fatigue	610	0
Muscle haemorrhage	1	0
Muscle mass	4	0
Muscle oedema	2	0
Muscle spasms	1489	0
Muscle swelling	16	0
Muscle tightness	85	0
Muscle twitching	225	0
<b>Muscle tone abnormalities</b>		
Muscle rigidity	29	0
Nuchal rigidity	10	0
Torticollis	6	0
Trismus	39	0
<b>Muscle weakness conditions</b>		
Muscular weakness	1094	0
<b>Musculoskeletal and connective tissue conditions NEC</b>		
Extremity contracture	1	0
Infantile back arching	1	0
Limb mass	2	0
Mandibular mass	1	0
Mastication disorder	1	0
Mobility decreased	67	0
Muscle contracture	3	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	1271	0
Somatic dysfunction	1	0

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Weight bearing difficulty	5	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Facial asymmetry	1	0
Head deformity	1	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Connective tissue inflammation	1	0
Dactylitis	1	0
Plantar fasciitis	2	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Amplified musculoskeletal pain syndrome	1	0
Back pain	3608	0
Flank pain	44	0
Growing pains	7	0
Limb discomfort	1294	0
Musculoskeletal chest pain	253	0
Musculoskeletal discomfort	72	0
Musculoskeletal pain	40	0
Neck pain	1737	0
Pain in extremity	12123	0
Rheumatic disorder	7	0
<b><i>Myopathies</i></b>		
Compartment syndrome	1	0
Myopathy	2	0
Rhabdomyolysis	5	0
<b><i>Osteoarthropathies</i></b>		
Nodal osteoarthritis	1	0
Osteoarthritis	16	0
Spinal osteoarthritis	2	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	16	0
<b><i>Rheumatoid arthropathies</i></b>		
Juvenile idiopathic arthritis	2	0
Rheumatoid arthritis	77	0
Still's disease	3	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	22	0
Fistula	1	0
Groin pain	101	0
Neck mass	9	0
Soft tissue disorder	1	0
Soft tissue mass	1	0
Soft tissue swelling	4	0
<b><i>Spine and neck deformities</i></b>		
Kyphosis	1	0
Scoliosis	2	0
Spinal stenosis	1	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	17	0
Arthritis reactive	14	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	3	0
Synovitis	6	0



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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Tendon disorders</i></b>		
Tendon discomfort	2	0
Tendon disorder	1	0
Tendon pain	11	0
Tendonitis	24	0
Tenosynovitis stenosaurs	1	0
Trigger finger	11	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>61025</b>	<b>0</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<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 malignant</i>		
Breast cancer	20	0
Breast cancer male	1	0
Breast cancer stage III	1	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Gastrointestinal neoplasms benign NEC</i>		
Gastrointestinal tract adenoma	1	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	2	0
<i>Hepatoblastomas</i>		
Hepatoblastoma	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	4	0
<i>Lip and oral cavity neoplasms benign</i>		
Papillary cystadenoma lymphomatosum	1	0
<i>Lip and oral cavity neoplasms malignant</i>		
Squamous cell carcinoma of the oral cavity	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	6	0
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Lymphoproliferative disorder in remission	1	0
<i>Metastases to specified sites</i>		
Metastases to central nervous system	1	1
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	2	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma	1	0
Metastatic neoplasm	3	0
Neoplasm malignant	3	1
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm recurrence	3	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Neuromas</i>		
Acoustic neuroma	2	0
<i>Ocular neoplasms benign</i>		
Eye naevus	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	1	0
Oesophageal carcinoma	1	0
Oesophageal squamous cell carcinoma	1	0
<i>Oncologic complications and emergencies</i>		

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Cancer fatigue	3	0
Cancer pain	1	0
Intracranial tumour haemorrhage	1	0
<b><i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i></b>		
Tonsil cancer	2	0
<b><i>Ovarian neoplasms malignant (excl germ cell)</i></b>		
Ovarian cancer	2	0
Ovarian cancer stage IV	1	0
<b><i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i></b>		
Pancreatic carcinoma	1	0
<b><i>Plasma cell myelomas</i></b>		
Plasma cell myeloma	1	0
<b><i>Prostatic neoplasms malignant</i></b>		
Prostate cancer	4	0
<b><i>Renal neoplasms malignant</i></b>		
Clear cell renal cell carcinoma	1	0
Metastatic renal cell carcinoma	1	0
Renal cancer	1	0
<b><i>Respiratory tract and pleural neoplasms malignancy unspecified NEC</i></b>		
Maxillofacial sinus neoplasm	1	0
<b><i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i></b>		
Bronchial carcinoma	4	0
Lung neoplasm malignant	3	0
<b><i>Salivary gland neoplasms malignant</i></b>		
Salivary gland cancer stage III	1	0
<b><i>Skin melanomas (excl ocular)</i></b>		
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	1	0
Malignant melanoma in situ	1	0
<b><i>Skin neoplasms benign</i></b>		
Haemangioma of skin	3	0
Melanocytic naevus	2	0
Skin papilloma	6	0
<b><i>Skin neoplasms malignant and unspecified (excl melanoma)</i></b>		
Basal cell carcinoma	1	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0
<b><i>Soft tissue neoplasms benign NEC</i></b>		
Knuckle pads	1	0
Lipoma	2	0
<b><i>Uterine neoplasms benign</i></b>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>116</b>	<b>2</b>

## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	7	0
Hyperreflexia	1	0
Hyporeflexia	6	0
Poor sucking reflex	1	0
Reflexes abnormal	1	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	16	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	19	0
<i><b>Acute polyneuropathies</b></i>		
Acute motor axonal neuropathy	2	0
Guillain-Barre syndrome	97	1
Miller Fisher syndrome	3	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i><b>Auditory nerve disorders</b></i>		
Acoustic neuritis	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Autonomic nervous system imbalance	6	0
Orthostatic intolerance	1	0
<i><b>Central nervous system aneurysms and dissections</b></i>		
Intracranial aneurysm	1	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Basal ganglia stroke	1	0
Basilar artery thrombosis	1	0
Brain stem haemorrhage	3	0
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	2	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	2	0
Cerebellar stroke	3	0
Cerebral artery embolism	1	0
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	1	0
Cerebral haematoma	4	0
Cerebral haemorrhage	59	21
Cerebral infarction	17	1
Cerebral ischaemia	2	0
Cerebral thrombosis	13	4
Cerebrovascular accident	341	20
Embolic stroke	6	0
Haemorrhage intracranial	17	1
Haemorrhagic cerebral infarction	1	1
Haemorrhagic stroke	14	3
Haemorrhagic transformation stroke	1	0
Intracranial haematoma	1	1
Intraventricular haemorrhage	2	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	36	1
Lacunar infarction	1	0
Lacunar stroke	5	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Subarachnoid haemorrhage	21	2
Thalamus haemorrhage	4	0
Thrombotic stroke	2	0
<b>Central nervous system inflammatory disorders NEC</b>		
Arachnoiditis	1	0
Central nervous system inflammation	4	0
Neurosarcoidosis	1	0
<b>Central nervous system vascular disorders NEC</b>		
Carotid artery stenosis	1	0
Cerebral amyloid angiopathy	2	0
Cerebral congestion	1	0
Cerebral small vessel ischaemic disease	1	0
Cerebral vasoconstriction	1	0
Cerebrovascular disorder	3	0
Internal carotid artery deformity	1	0
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	59	7
Cerebral venous thrombosis	11	0
Superior sagittal sinus thrombosis	12	2
Transverse sinus thrombosis	1	0
<b>Cervical spinal cord and nerve root disorders</b>		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	5	0
<b>Choreiform movements</b>		
Chorea	1	0
Sydenham's chorea	1	0
<b>Chronic polyneuropathies</b>		
Diabetic neuropathy	2	0
<b>Coma states</b>		
Coma	7	0
Diabetic coma	2	0
<b>Coordination and balance disturbances</b>		
Ataxia	10	0
Balance disorder	424	0
Cerebellar ataxia	1	0
Coordination abnormal	62	0
Dysstasia	51	0
Nystagmus	9	0
<b>Cortical dysfunction NEC</b>		
Aphasia	45	0
Apraxia	1	0
Dysgraphia	1	0
Dyslexia	2	0
Dyspraxia	3	0
Neurologic neglect syndrome	2	0
Visuospatial deficit	2	0
<b>Cranial nerve disorders NEC</b>		
Cranial nerve disorder	1	0
Paresis cranial nerve	1	0
<b>Dementia (excl Alzheimer's type)</b>		
Dementia	9	0
Dementia with Lewy bodies	1	0
Frontotemporal dementia	1	0

## Case Series Drug Analysis Print

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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Senile dementia	1	0
Vascular dementia	3	0
<b><i>Demyelinating disorders NEC</i></b>		
Acute disseminated encephalomyelitis	2	0
Demyelination	3	0
<b><i>Disturbances in consciousness NEC</i></b>		
Altered state of consciousness	8	0
Consciousness fluctuating	3	0
Depressed level of consciousness	48	0
Lethargy	3133	0
Loss of consciousness	557	0
Postictal state	1	0
Sedation	5	0
Somnolence	1091	1
Stupor	4	0
Syncope	1435	0
<b><i>Disturbances in sleep phase rhythm</i></b>		
Advanced sleep phase	1	0
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	1	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Akathisia	9	0
Bradykinesia	15	0
Clumsiness	17	0
Dyskinesia	65	0
Extrapyramidal disorder	16	0
Fine motor skill dysfunction	5	0
Hyperkinesia	15	0
Hypokinesia	20	0
Motor dysfunction	7	0
Movement disorder	36	0
Psychomotor hyperactivity	26	0
<b><i>Dystonias</i></b>		
Dystonia	9	0
Dystonic tremor	3	0
Opisthotonus	4	0
<b><i>Encephalitis NEC</i></b>		
Noninfective encephalitis	3	0
<b><i>Encephalopathies NEC</i></b>		
Autoimmune encephalopathy	2	0
Encephalopathy	3	0
Hypoxic-ischaemic encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<b><i>Encephalopathies toxic and metabolic</i></b>		
Hepatic encephalopathy	2	0
<b><i>Eye movement disorders</i></b>		
IIIrd nerve paralysis	3	0
VIth nerve paralysis	2	0
<b><i>Facial cranial nerve disorders</i></b>		
Facial nerve disorder	2	0
Facial paralysis	266	0
Facial paresis	49	0
Facial spasm	17	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	42	0
<b><i>Headaches NEC</i></b>		
Cervicogenic headache	2	0
Cluster headache	389	0
Cold-stimulus headache	33	0
Drug withdrawal headache	12	0
Exertional headache	5	0
External compression headache	2	0
Headache	53282	1
Medication overuse headache	9	0
New daily persistent headache	6	0
Occipital neuralgia	8	0
Ophthalmoplegic migraine	1	0
Post-traumatic headache	2	0
Primary headache associated with sexual activity	5	0
Sinus headache	565	0
Tension headache	820	0
Thunderclap headache	18	0
Vascular headache	40	0
<b><i>Hydrocephalic conditions</i></b>		
Hydrocephalus	4	0
<b><i>Hypoglossal nerve disorders</i></b>		
Tongue paralysis	3	0
<b><i>Increased intracranial pressure disorders</i></b>		
Brain compression	1	0
Brain oedema	10	0
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	7	0
<b><i>Intellectual disabilities</i></b>		
Intellectual disability	7	0
<b><i>Lumbar spinal cord and nerve root disorders</i></b>		
Sciatica	68	0
<b><i>Memory loss (excl dementia)</i></b>		
Amnesia	129	0
Memory impairment	112	0
Transient global amnesia	7	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	68	1
Disturbance in attention	315	0
Judgement impaired	3	0
Mental impairment	57	0
<b><i>Migraine headaches</i></b>		
Basilar migraine	3	0
Hemiplegic migraine	12	0
Migraine	4257	0
Migraine with aura	168	0
Migraine without aura	29	0
Retinal migraine	31	0
Status migrainosus	1	0
Typical aura without headache	6	0
Vestibular migraine	9	0
<b><i>Mononeuropathies</i></b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Carpal tunnel syndrome	11	0
Diabetic mononeuropathy	1	0
Mononeuritis	2	0
Nerve compression	15	0
Peroneal nerve palsy	4	0
Piriformis syndrome	1	0
Radial nerve palsy	1	0
Sciatic nerve neuropathy	1	0
Ulnar nerve palsy	1	0
Ulnar neuritis	1	0
Ulnar tunnel syndrome	1	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	2	0
Multiple sclerosis	33	0
Multiple sclerosis relapse	25	0
Relapsing multiple sclerosis	1	0
Uhthoff's phenomenon	3	0
<b>Muscle tone abnormal</b>		
Hypotonia	16	0
Serotonin syndrome	1	0
Stiff leg syndrome	4	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	25	1
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	1	0
Hypersomnia	109	0
Narcolepsy	9	0
<b>Nervous system cysts and polyps</b>		
Pineal gland cyst	1	0
<b>Nervous system disorders NEC</b>		
Brain stem syndrome	1	0
Cerebral disorder	1	0
Nervous system disorder	15	0
Psychomotor skills impaired	3	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	2	0
Tunnel vision	10	0
Visual field defect	11	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	13517	0
Dizziness exertional	60	0
Dizziness postural	1446	1
Drooling	9	0
Exaggerated startle response	3	0
Fontanelle bulging	2	0
Head discomfort	246	0
Hyporesponsive to stimuli	1	0
Infant irritability	4	0
Meningism	1	0
Myoclonus	15	0
Neurological decompensation	2	0
Neurological symptom	46	0
Patient elopement	1	0



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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Persistent postural-perceptual dizziness	14	0
Pleocytosis	1	0
Presyncope	374	0
Sensory overload	5	0
Slow response to stimuli	3	0
Tongue biting	5	0
Unresponsive to stimuli	55	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	15	0
Muscle spasticity	14	0
Neuromuscular pain	2	0
Neuromyopathy	2	0
Neuromyotonia	1	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	4	0
Myasthenia gravis crisis	1	0
<b>Olfactory nerve disorders</b>		
Anosmia	155	0
Hyposmia	8	0
Parosmia	214	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	10	0
<b>Paraesthesias and dysaesthesias</b>		
Anaesthesia	2	0
Burning feet syndrome	9	0
Burning sensation	386	0
Burning sensation mucosal	1	0
Dysaesthesia	5	0
Formication	31	0
Hemianaesthesia	2	0
Hyperaesthesia	173	0
Hypoaesthesia	2584	0
Lhermitte's sign	1	0
Paraesthesia	4447	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	16	0
Hemiparesis	37	0
Hemiplegia	12	0
Monoparesis	45	0
Monoplegia	58	0
Paralysis	151	0
Paraparesis	5	0
Paraplegia	1	0
Paresis	5	0
Peripheral nerve palsy	1	0
Postictal paralysis	1	0
Quadriplegia	1	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	109	0
Parkinson's disease	11	0
Parkinsonism	10	0
Reduced facial expression	3	0
<b>Partial complex seizures</b>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Dreamy state	11	0
Focal dyscognitive seizures	3	0
Temporal lobe epilepsy	3	0
<b>Partial simple seizures NEC</b>		
Simple partial seizures	3	0
<b>Peripheral neuropathies NEC</b>		
Autoimmune neuropathy	2	0
Neuritis	3	0
Neuropathy peripheral	81	0
Peripheral sensory neuropathy	2	0
Polyneuropathy	4	0
Small fibre neuropathy	2	0
Thoracic outlet syndrome	1	0
<b>Seizures and seizure disorders NEC</b>		
Alcoholic seizure	1	0
Atonic seizures	5	0
Change in seizure presentation	2	0
Clonic convulsion	6	0
Drug withdrawal convulsions	2	0
Epilepsy	133	0
Epileptic aura	1	0
Febrile convulsion	61	0
Migraine-triggered seizure	1	0
Myoclonic epilepsy	3	0
Partial seizures	30	0
Psychogenic seizure	5	0
Seizure	613	2
Seizure anoxic	1	0
Seizure cluster	4	0
Seizure like phenomena	2	0
Status epilepticus	46	1
Tonic clonic movements	1	0
Tonic convulsion	19	0
<b>Sensory abnormalities NEC</b>		
Ageusia	626	0
Allodynia	38	0
Aura	11	0
Central pain syndrome	2	0
Complex regional pain syndrome	7	0
Dysgeusia	1255	0
Hypogeusia	2	0
Intercostal neuralgia	1	0
Loss of proprioception	2	0
Neuralgia	604	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	11	0
Post herpetic neuralgia	2	0
Restless arm syndrome	9	0
Restless legs syndrome	215	0
Sensory disturbance	41	0
Sensory loss	86	0
Taste disorder	305	0
<b>Sleep disturbances NEC</b>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Microsleep	1	0
Poor quality sleep	461	0
Sleep deficit	28	0
<b><i>Speech and language abnormalities</i></b>		
Dysarthria	151	0
Incoherent	4	0
Language disorder	2	0
Slow speech	12	0
Speech disorder	28	0
<b><i>Spinal cord and nerve root disorders NEC</i></b>		
Cauda equina syndrome	1	0
Myelopathy	2	0
Radiculitis brachial	3	0
Radiculopathy	1	0
<b><i>Structural brain disorders NEC</i></b>		
Brain injury	10	0
Intracranial mass	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	161	0
<b><i>Tremor (excl congenital)</i></b>		
Action tremor	1	0
Asterixis	1	0
Essential tremor	3	0
Head titubation	9	0
Intention tremor	1	0
Postural tremor	1	0
Resting tremor	4	0
Tremor	7214	2
<b><i>Trigeminal disorders</i></b>		
Facial neuralgia	16	0
Numb chin syndrome	1	0
Trigeminal neuralgia	31	0
Trigeminal neuritis	1	0
Trigeminal palsy	1	0
<b><i>Vagus nerve disorders</i></b>		
Vagus nerve paralysis	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>105996</b>	<b>76</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Abortions spontaneous</b></i>		
Abortion spontaneous	19	0
<i><b>Foetal position and presentation abnormalities</b></i>		
Face presentation	2	0
<i><b>Labour onset and length abnormalities</b></i>		
Precipitate labour	1	0
Premature labour	3	0
Premature rupture of membranes	1	0
<i><b>Maternal complications of labour NEC</b></i>		
Uterine contractions abnormal	1	0
<i><b>Maternal complications of pregnancy NEC</b></i>		
Hyperemesis gravidarum	2	0
Morning sickness	22	0
Pelvic girdle pain	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Pregnancy	5	0
Uterine contractions during pregnancy	1	0
<i><b>Pregnancy complicated by maternal disorders</b></i>		
Gestational diabetes	3	0
<i><b>Stillbirth and foetal death</b></i>		
Stillbirth	2	0
<i><b>Unintended pregnancies</b></i>		
Pregnancy after post coital contraception	1	0
Pregnancy on contraceptive	1	0
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>66</b>	<b>0</b>

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b><i>Device electrical issues</i></b>		
Device electrical impedance issue	1	0
<b><i>Device incompatibility issues</i></b>		
Patient-device incompatibility	1	0
<b><i>Device issues NEC</i></b>		
Device issue	2	0
Device leakage	2	0
<b><i>Device malfunction events NEC</i></b>		
Oversensing	15	0
Stent malfunction	1	0
Thrombosis in device	13	0
Undersensing	2	0
<b><i>Device physical property and chemical issues</i></b>		
Needle issue	2	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	1	0
<b><i>Product label issues</i></b>		
Product label issue	1	0
<b><i>Product physical issues</i></b>		
Product physical issue	1	0
Product taste abnormal	2	0
<b><i>Product quality issues NEC</i></b>		
Product origin unknown	1	0
Suspected product quality issue	2	0
<b>null SOC TOTAL</b>	<b>47</b>	<b>0</b>

## Case Series Drug Analysis Print

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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	8	0
Breath holding	2	0
Staring	6	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder with depressed mood	4	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	5	0
Constricted affect	5	0
Flat affect	6	0
Inappropriate affect	9	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	3	0
<b><i>Anxiety disorders NEC</i></b>		
Anxiety disorder	2	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	119	0
Anxiety	494	0
Nervousness	411	0
Stress	33	0
Tension	33	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	7	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	5	0
Asocial behaviour	1	0
Aversion	1	0
Impatience	1	0
Indifference	4	0
Paranoia	20	0
Personality change	1	0
Social avoidant behaviour	3	0
Soliloquy	2	0
Violence-related symptom	2	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	4	0
Bipolar disorder	2	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Change in sustained attention	1	0
Daydreaming	8	0
Mental fatigue	256	0
<b><i>Communications disorders</i></b>		
Communication disorder	1	0
Mutism	2	0
Speech sound disorder	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	1100	1
Disorientation	445	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	2	0
<b><i>Deliria</i></b>		

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Delirium	329	0
Delirium febrile	2	0
<b>Delusional symptoms</b>		
Delusion	26	0
Thought withdrawal	1	0
<b>Depressive disorders</b>		
Agitated depression	3	0
Depression	263	0
Depression suicidal	6	0
Major depression	13	0
Mixed anxiety and depressive disorder	1	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	9	0
Dissociation	33	0
Dissociative disorder	1	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	16	0
Insomnia	1941	0
Middle insomnia	42	0
Terminal insomnia	5	0
<b>Dyssomnias</b>		
Dyssomnia	2	0
<b>Eating disorders NEC</b>		
Eating disorder	3	0
<b>Emotional and mood disturbances NEC</b>		
Anger	40	0
Dysphoria	1	0
Emotional disorder	55	0
Emotional distress	40	0
Emotional poverty	2	0
Euphoric mood	45	0
Frustration tolerance decreased	2	0
Irritability	162	0
Mood altered	35	0
<b>Factitious disorders</b>		
Factitious disorder	4	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	9	0
Fear of death	6	0
Fear of disease	1	0
Fear of eating	1	0
Fear of falling	2	0
Fear of injection	1	0
Fear of open spaces	1	0
Paruresis	1	0
Performance fear	1	0
Phobia	2	0
Phonophobia	3	0
<b>Fluctuating mood symptoms</b>		
Mood swings	32	0
<b>Hallucinations (excl sleep-related)</b>		

## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Hallucination	639	0
Hallucination, auditory	24	0
Hallucination, olfactory	5	0
Hallucination, tactile	1	0
Hallucination, visual	34	0
Hallucinations, mixed	6	0
<b>Impulse control disorders</b>		
Impulse-control disorder	2	0
Impulsive behaviour	1	0
<b>Increased physical activity levels</b>		
Restlessness	319	0
<b>Infancy, childhood and adolescence psychiatric disorders NEC</b>		
Emotional disorder of childhood	1	0
<b>Mental disorders NEC</b>		
Mental disorder	4	0
Mental status changes	2	0
<b>Mental disorders due to a general medical condition NEC</b>		
Neuropsychiatric symptoms	1	0
<b>Mood alterations with depressive symptoms</b>		
Anhedonia	3	0
Decreased interest	10	0
Depressed mood	288	0
Depressive symptom	1	0
Feeling of despair	12	0
Negative thoughts	5	0
Sense of a foreshortened future	1	0
Tearfulness	67	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	1	0
Mania	18	0
<b>Mood disorders NEC</b>		
Affective disorder	1	0
Apathy	25	0
Listless	88	0
<b>Narcolepsy and associated conditions</b>		
Hypnagogic hallucination	4	0
Sleep attacks	1	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Compulsive shopping	1	0
Dermatillomania	1	0
Obsessive thoughts	1	0
Obsessive-compulsive disorder	1	0
<b>Orgasmic disorders and disturbances</b>		
Orgasmic sensation decreased	4	0
Premature ejaculation	1	0
<b>Panic attacks and disorders</b>		
Limited symptom panic attack	1	0
Panic attack	152	0
Panic disorder	2	0
Panic reaction	20	0
<b>Parasomnias</b>		
Abnormal dreams	227	0
Confusional arousal	2	0



## Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Exploding head syndrome	4	0
Nightmare	302	0
Rapid eye movements sleep abnormal	2	0
Sleep inertia	1	0
Sleep talking	10	0
Sleep terror	34	0
Sleep-related eating disorder	2	0
Somnambulism	5	0
<b>Perception disturbances NEC</b>		
Autoscopy	14	0
Deja vu	2	0
Derealisation	9	0
Flashback	2	0
Illusion	9	0
Time perception altered	5	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	31	0
<b>Psychiatric symptoms NEC</b>		
Helplessness	1	0
Hypervigilance	8	0
Psychiatric symptom	2	0
Psychological trauma	2	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	22	0
<b>Schizoaffective and schizophreniform disorders</b>		
Schizoaffective disorder	1	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	3	0
<b>Sexual desire disorders</b>		
Libido decreased	3	0
Libido increased	4	0
Loss of libido	20	0
<b>Sleep disorders NEC</b>		
Sleep disorder	214	0
Sleep disorder due to general medical condition, insomnia type	1	0
<b>Somatic symptom disorders</b>		
Conversion disorder	5	0
Habit cough	24	0
Illness anxiety disorder	1	0
Somatic symptom disorder	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	5	0
Logorrhoea	2	0
Pedantic speech	1	0
Poverty of speech	1	0
Verbigeration	1	0
<b>Speech articulation and rhythm disturbances</b>		

## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021

Data Lock Date: 05-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Dysphemia	11	0
Lack of spontaneous speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Bruxism	16	0
Head banging	26	0
Waxy flexibility	1	0
<b><i>Stress disorders</i></b>		
Acute stress disorder	2	0
Burnout syndrome	6	0
Hyperarousal	2	0
Post-traumatic stress disorder	10	0
<b><i>Substance related and addictive disorders</i></b>		
Alcohol abuse	1	0
Alcohol use disorder	2	0
Alcoholism	1	0
Drug dependence	1	0
Substance abuse	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Completed suicide	2	0
Intentional self-injury	5	0
Self-injurious ideation	1	0
Suicidal behaviour	2	0
Suicidal ideation	50	0
Suicide attempt	3	0
Suicide threat	1	0
<b><i>Thinking disturbances</i></b>		
Bradyphrenia	48	0
Confabulation	1	0
Impaired reasoning	1	0
Intrusive thoughts	2	0
Morbid thoughts	2	0
Tachyphrenia	16	0
Thinking abnormal	13	0
Thought blocking	1	0
<b><i>Tic disorders</i></b>		
Tic	4	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>9124</b>	<b>1</b>

## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021  
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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	4	0
Bladder irritation	3	0
Bladder pain	30	0
Bladder spasm	1	0
Dysuria	49	0
Incontinence	48	0
Micturition disorder	2	0
Micturition frequency decreased	1	0
Micturition urgency	69	0
Mixed incontinence	1	0
Pollakiuria	181	0
Urethral pain	1	0
Urge incontinence	1	0
Urinary hesitation	3	0
Urinary incontinence	67	0
Urinary retention	43	0
Urine flow decreased	5	0
<i><b>Bladder disorders NEC</b></i>		
Bladder dilatation	1	0
Bladder disorder	9	0
Urinary bladder haemorrhage	3	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	4	0
Cystitis noninfective	1	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Urinary tract disorder	1	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Anti-glomerular basement membrane disease	1	0
IgA nephropathy	2	0
Nephrotic syndrome	3	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Automatic bladder	1	0
Bladder dysfunction	1	0
Hypertonic bladder	9	0
Loss of bladder sensation	8	0
Neurogenic bladder	1	0
<i><b>Nephritis NEC</b></i>		
Nephritis	4	0
Tubulointerstitial nephritis	1	0
<i><b>Nephropathies and tubular disorders NEC</b></i>		
Nephropathy	1	0
<i><b>Renal disorders NEC</b></i>		
Oedematous kidney	1	0
Renal disorder	4	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	20	0
Anuria	2	0
Chronic kidney disease	4	0
Oliguria	9	0
Renal failure	7	1
Renal impairment	5	0
Renal injury	3	0

## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Renal &amp; urinary disorders cont'd</i>		
<b><i>Renal lithiasis</i></b>		
Nephrolithiasis	2	0
<b><i>Renal structural abnormalities and trauma</i></b>		
Kidney enlargement	1	0
Renal atrophy	1	0
<b><i>Renal vascular and ischaemic conditions</i></b>		
Renal infarct	2	0
Renal vein thrombosis	3	0
<b><i>Structural and obstructive urethral disorders (excl congenital)</i></b>		
Urethral spasm	1	0
<b><i>Ureteric disorders NEC</i></b>		
Ureteral disorder	2	0
<b><i>Urinary abnormalities</i></b>		
Chromaturia	66	0
Glycosuria	1	0
Haematuria	22	0
Proteinuria	2	0
Urine abnormality	10	0
Urine odour abnormal	17	0
<b><i>Urinary tract signs and symptoms NEC</i></b>		
Haemorrhage urinary tract	13	0
Nocturia	10	0
Polyuria	22	0
Renal colic	2	0
Renal pain	599	0
Urinary tract discomfort	1	0
Urinary tract pain	4	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1396</b>	<b>1</b>

## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021

Data Lock Date: 05-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	1	0
<i><b>Breast disorders NEC</b></i>		
Breast disorder	1	0
Breast enlargement	3	0
Breast mass	14	0
Gynaecomastia	2	0
<i><b>Breast infections and inflammations</b></i>		
Breast inflammation	1	0
Nipple inflammation	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	1	0
Breast discomfort	3	0
Breast engorgement	1	0
Breast induration	1	0
Breast oedema	1	0
Breast pain	177	0
Breast swelling	23	0
Breast tenderness	19	0
Nipple pain	15	0
Nipple swelling	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation delayed	1	0
Ejaculation disorder	1	0
Ejaculation failure	2	0
Erectile dysfunction	39	0
Erection increased	2	0
Organic erectile dysfunction	13	0
Painful erection	1	0
Priapism	1	0
Retrograde ejaculation	1	0
Spontaneous penile erection	2	0
<i><b>Fallopian tube and ovary infections and inflammations</b></i>		
Noninfective oophoritis	1	0
<i><b>Lactation disorders</b></i>		
Lactation puerperal increased	1	0
Suppressed lactation	7	0
<i><b>Menopausal effects NEC</b></i>		
Artificial menopause	2	0
Menopausal symptoms	10	0
Menopause delayed	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	19	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal withdrawal bleeding	1	0
Dysmenorrhoea	48	0
Menstrual disorder	71	0
Menstruation irregular	88	0
Metrorrhagia	38	0
Premenstrual pain	6	0
Premenstrual syndrome	1	0
Withdrawal bleed	2	0
<i><b>Menstruation with decreased bleeding</b></i>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Amenorrhoea	30	0
Hypomenorrhoea	32	0
Menstruation delayed	110	0
Oligomenorrhoea	9	0
<b>Menstruation with increased bleeding</b>		
Menometrorrhagia	1	0
Menorrhagia	157	0
Polymenorrhoea	17	0
<b>Ovarian and fallopian tube cysts and neoplasms</b>		
Ovarian cyst ruptured	1	0
Polycystic ovaries	4	0
<b>Ovarian and fallopian tube disorders NEC</b>		
Ovarian enlargement	1	0
Ovarian necrosis	1	0
Ovarian vein thrombosis	3	0
Ovulation pain	1	0
Premature ovulation	2	0
<b>Pelvic prolapse conditions</b>		
Vaginal prolapse	1	0
<b>Pelvis and broad ligament disorders NEC</b>		
Adnexa uteri pain	10	0
Pelvic haematoma	1	0
Pelvic haemorrhage	3	0
<b>Penile and scrotal infections and inflammations</b>		
Balanoposthitis	1	0
<b>Penile disorders NEC (excl erection and ejaculation)</b>		
Penile blister	4	0
Penile burning sensation	1	0
Penile curvature	1	0
Penile oedema	2	0
Penile pain	1	0
Penis disorder	2	0
Peyronie's disease	2	0
<b>Prostate and seminal vesicles infections and inflammations</b>		
Prostatitis	4	0
<b>Prostatic neoplasms and hypertrophy</b>		
Benign prostatic hyperplasia	1	0
<b>Reproductive tract disorders NEC (excl neoplasms)</b>		
Female genital tract fistula	1	0
Genital blister	3	0
Genital haemorrhage	3	0
Genital hyperaesthesia	1	0
Genital hypoaesthesia	1	0
Genital paraesthesia	1	0
Genital ulceration	7	0
<b>Reproductive tract infections and inflammations NEC</b>		
Genital tract inflammation	1	0
<b>Reproductive tract signs and symptoms NEC</b>		
Genital burning sensation	5	0
Genital discomfort	3	0
Genital erythema	1	0
Genital pain	2	0
Pelvic discomfort	2	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
Pelvic pain	62	0
Pruritus genital	2	0
<b>Scrotal disorders NEC</b>		
Scrotal oedema	1	0
Scrotal pain	6	0
Scrotal swelling	4	0
<b>Sexual function and fertility disorders NEC</b>		
Dyspareunia	2	0
Female sexual dysfunction	1	0
Sexual dysfunction	2	0
<b>Spermatogenesis and semen disorders</b>		
Haematospermia	3	0
Semen discolouration	1	0
<b>Testicular and epididymal disorders NEC</b>		
Testicular disorder	2	0
Testicular mass	1	0
Testicular pain	50	0
Testicular retraction	1	0
Testicular swelling	6	0
<b>Testicular and epididymal neoplasms</b>		
Epididymal cyst	1	0
<b>Uterine disorders NEC</b>		
Adenomyosis	1	0
Endometriosis	16	0
Uterine enlargement	1	0
Uterine haemorrhage	7	0
Uterine pain	2	0
<b>Uterine tone disorders</b>		
Uterine spasm	6	0
<b>Vaginal and vulval infections and inflammations</b>		
Vulvovaginal inflammation	2	0
<b>Vulvovaginal cysts and neoplasms</b>		
Vaginal cyst	1	0
<b>Vulvovaginal disorders NEC</b>		
Vaginal haemorrhage	165	0
Vaginal ulceration	2	0
Vulval disorder	2	0
Vulval haemorrhage	6	0
Vulval ulceration	2	0
Vulvovaginal ulceration	1	0
<b>Vulvovaginal signs and symptoms</b>		
Enlarged clitoris	1	0
Vaginal discharge	19	0
Vaginal lesion	3	0
Vulval oedema	1	0
Vulvovaginal burning sensation	6	0
Vulvovaginal discomfort	1	0
Vulvovaginal dryness	1	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	9	0
Vulvovaginal pruritus	1	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	3	0

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>1465</b>	<b>0</b>



## Case Series Drug Analysis Print

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Report Run Date: 12-Apr-2021  
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	7	0
Apnoeic attack	1	0
Dyspnoea	3433	3
Dyspnoea at rest	8	0
Dyspnoea exertional	19	0
Dyspnoea paroxysmal nocturnal	1	0
Grunting	1	0
Hyperventilation	53	0
Hypopnoea	130	0
Hypoventilation	1	0
Irregular breathing	16	0
Mouth breathing	7	0
Orthopnoea	2	0
Respiration abnormal	62	0
Respiratory arrest	12	0
Respiratory distress	4	0
Respiratory fatigue	2	0
Sleep apnoea syndrome	16	0
Tachypnoea	27	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchiectasis	10	0
<i><b>Bronchospasm and obstruction</b></i>		
Aspirin-exacerbated respiratory disease	1	0
Asthma	296	0
Asthma late onset	1	0
Asthmatic crisis	3	0
Bronchitis chronic	1	0
Bronchospasm	12	0
Chronic obstructive pulmonary disease	22	2
Cough variant asthma	5	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	345	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Hypercapnia	1	0
Hypoxia	37	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	3	0
Cough	2260	0
Haemoptysis	38	0
Productive cough	91	0
Sputum discoloured	6	0
Sputum increased	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Reflux laryngitis	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngeal oedema	2	0
Laryngospasm	1	0
Stridor	13	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		

## Case Series Drug Analysis Print

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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Alveolitis	2	0
Pneumonia aspiration	10	4
Pneumonitis	12	0
<b>Lower respiratory tract signs and symptoms</b>		
Hiccups	25	0
Lower respiratory tract congestion	3	0
Lung opacity	3	0
Pleuritic pain	13	0
Pulmonary haemorrhage	1	0
Pulmonary pain	115	0
<b>Nasal congestion and inflammations</b>		
Nasal congestion	302	0
Nasal inflammation	4	0
Rhinitis allergic	11	0
Rhinitis perennial	1	0
<b>Nasal disorders NEC</b>		
Epistaxis	759	0
Intranasal hypoaesthesia	1	0
Nasal crusting	4	0
Nasal cyst	1	0
Nasal disorder	1	0
Nasal dryness	30	0
Nasal odour	2	0
Nasal oedema	6	0
Nasal pruritus	4	0
Nasal ulcer	2	0
<b>Neonatal hypoxic conditions</b>		
Gasping syndrome	1	0
<b>Paranasal sinus disorders (excl infections and neoplasms)</b>		
Paranasal sinus haemorrhage	3	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	5	0
Sinus congestion	42	0
Sinus disorder	7	0
<b>Parenchymal lung disorders NEC</b>		
Emphysema	1	0
Idiopathic pulmonary fibrosis	1	0
Interstitial lung disease	3	0
Lung consolidation	1	0
Lung infiltration	1	0
Pulmonary cavitation	3	0
<b>Pharyngeal disorders (excl infections and neoplasms)</b>		
Oropharyngeal swelling	1	0
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	23	0
Pharyngeal oedema	10	0
Pharyngeal paraesthesia	22	0
Pharyngeal swelling	151	0
Pharyngeal ulceration	8	0
Tonsillar disorder	1	0
Tonsillar erythema	4	0
Tonsillar hypertrophy	34	0

## Case Series Drug Analysis Print

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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Tonsillar inflammation	3	0
<b><i>Pleural infections and inflammations</i></b>		
Lupus pleurisy	1	0
Pleurisy	17	0
<b><i>Pneumothorax and pleural effusions NEC</i></b>		
Pleural effusion	7	0
Pneumothorax	2	0
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary hypertension	2	1
<b><i>Pulmonary oedemas</i></b>		
Acute pulmonary oedema	2	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	12	0
Pulmonary oedema	10	0
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary embolism	378	40
Pulmonary infarction	1	1
Pulmonary thrombosis	6	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Respiratory failure	8	2
<b><i>Respiratory signs and symptoms NEC</i></b>		
Allergic respiratory symptom	3	0
Diaphragmalgia	11	0
Painful respiration	2	0
Respiratory symptom	11	0
Suffocation feeling	2	0
<b><i>Respiratory tract disorders NEC</i></b>		
Aspiration	5	2
Chronic respiratory disease	1	0
Lung disorder	4	0
Respiratory disorder	3	0
Respiratory tract congestion	4	0
Respiratory tract haemorrhage	1	0
Respiratory tract irritation	5	0
<b><i>Thoracic musculoskeletal disorders</i></b>		
Respiratory muscle weakness	1	0
<b><i>Tracheal disorders (excl infections and neoplasms)</i></b>		
Tracheal fistula	1	0
Tracheal pain	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	42	0
Catarrh	37	0
Choking	11	0
Choking sensation	5	0
Dry throat	170	0
Dysphonia	78	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	13	0
Laryngeal pain	1	0
Nasal discomfort	60	0
Oropharyngeal blistering	15	0
Oropharyngeal discomfort	16	0
Oropharyngeal pain	2705	0

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021

Data Lock Date: 05-Apr-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Paranasal sinus discomfort	30	0
Rhinalgia	21	0
Rhinorrhoea	1094	0
Sinus pain	354	0
Sneezing	280	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	125	0
Throat lesion	1	0
Throat tightness	116	0
Upper respiratory tract congestion	1	0
Upper-airway cough syndrome	12	0
Yawning	49	0
<b>Respiratory disorders SOC TOTAL</b>	<b>14344</b>	<b>55</b>

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
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Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	33	0
Acne cystic	1	0
Dermatitis acneiform	2	0
<b><i>Alopecias</i></b>		
Alopecia	61	0
Alopecia areata	2	0
Alopecia totalis	1	0
Alopecia universalis	1	0
Diffuse alopecia	1	0
Madarosis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	186	0
Circumoral oedema	1	0
Idiopathic angioedema	3	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	2	0
Cold sweat	1184	0
Hyperhidrosis	6506	0
Hypohidrosis	2	0
Miliaria	121	0
Night sweats	1240	0
Sweat discolouration	1	0
Sweat gland disorder	1	0
<b><i>Bullous conditions</i></b>		
Blister	198	0
Blister rupture	2	0
Blood blister	20	0
Dermatitis bullous	6	0
Dermatitis herpetiformis	1	0
Erythema multiforme	13	0
Oedema blister	1	0
Pemphigoid	4	0
Pemphigus	1	0
Stevens-Johnson syndrome	4	0
<b><i>Connective tissue disorders</i></b>		
Subacute cutaneous lupus erythematosus	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	195	0
Macule	4	0
Myxoid cyst	1	0
Pain of skin	641	0
Papule	30	0
Peau d'orange	1	0
Scab	10	0
Scar pain	6	0
Sensitive skin	393	0
Skin burning sensation	340	0
Skin discolouration	76	0
Skin disorder	10	0
Skin fissures	6	0
Skin fragility	1	0
Skin indentation	2	0

## Case Series Drug Analysis Print

### Name: COVID-19 vaccine AstraZeneca analysis print

Report Run Date: 12-Apr-2021  
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 05-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin induration	10	0
Skin lesion	11	0
Skin necrosis	2	0
Skin odour abnormal	30	0
Skin plaque	1	0
Skin reaction	144	0
Skin sensitisation	62	0
Skin swelling	57	0
Skin texture abnormal	1	0
Skin tightness	14	0
Skin warm	387	0
Skin weeping	1	0
Sticky skin	1	0
Yellow skin	17	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	96	0
Dermatitis allergic	159	0
Dermatitis atopic	12	0
Dermatitis contact	1	0
Dermatitis diaper	1	0
Dyshidrotic eczema	2	0
Eczema	99	0
Eczema asteatotic	5	0
Eczema nummular	1	0
Eczema weeping	1	0
Hand dermatitis	3	0
Intertrigo	2	0
Perioral dermatitis	3	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	3	0
Skin irritation	74	0
Stasis dermatitis	1	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	22	0
Drug reaction with eosinophilia and systemic symptoms	8	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<b><i>Erythemas</i></b>		
Erythema	2119	0
Erythema ab igne	1	0
Palmar erythema	4	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	2	0
Exfoliative rash	9	0
Skin exfoliation	55	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Granuloma annulare	2	0
<b><i>Hyperpigmentation disorders</i></b>		
Solar lentigo	2	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	1	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin hypopigmentation	1	0
Vitiligo	5	0
<b>Lipodystrophies</b>		
Lipoatrophy	2	0
Lipohypertrophy	2	0
<b>Nail and nail bed conditions (excl infections and infestations)</b>		
Nail bed disorder	1	0
Nail bed tenderness	1	0
Nail discolouration	4	0
Nail disorder	1	0
Nail hypertrophy	1	0
Nail pigmentation	1	0
Nail pitting	1	0
Nail ridging	1	0
Onychalgia	2	0
Onychoclasia	3	0
Onychomadesis	1	0
<b>Panniculitides</b>		
Erythema nodosum	5	0
<b>Papulosquamous conditions</b>		
Erythema annulare	1	0
Lichen planus	5	0
Lichen sclerosus	2	0
Pityriasis rosea	8	0
Pityriasis rubra pilaris	1	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	95	0
Polymorphic light eruption	1	0
<b>Pigmentation changes NEC</b>		
Pigmentation disorder	4	0
<b>Pilar disorders NEC</b>		
Hair colour changes	1	0
Hair disorder	1	0
Hair growth abnormal	2	0
Hair texture abnormal	1	0
Piloerection	62	0
Pseudofolliculitis	1	0
Trichodynia	3	0
<b>Pruritus NEC</b>		
Itching scar	1	0
Pruritus	4436	0
Pruritus allergic	1	0
<b>Psoriatic conditions</b>		
Guttate psoriasis	10	0
Psoriasis	60	0
Pustular psoriasis	1	0
<b>Purpura and related conditions</b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	2	0
Petechiae	70	0
Purpura	35	1
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	4	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash	4347	0
Rash erythematous	1289	0
Rash macular	379	0
Rash maculo-papular	29	0
Rash morbilliform	19	0
Rash papular	234	0
Rash pruritic	1005	0
Rash rubelliform	1	0
Rash scarlatiniform	1	0
Rash vesicular	36	0
Systemic lupus erythematosus rash	3	0
<b>Rosaceas</b>		
Rosacea	15	0
<b>Scaly conditions</b>		
Pityriasis	1	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	3	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	6	0
Skin mass	17	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Diabetic foot	1	0
Mucocutaneous ulceration	2	0
Pyoderma gangrenosum	1	0
Skin erosion	26	0
Skin ulcer	12	0
<b>Skin cysts and polyps</b>		
Dermal cyst	5	0
<b>Skin dystrophies</b>		
Skin wrinkling	2	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	4	0
Skin haemorrhage	10	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Skin hypoplasias and atrophies</b>		
Skin atrophy	3	0
Skin striae	1	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	2	0
Needle track marks	3	0
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	1	0
Leukoplakia	1	0
<b>Skin vascular conditions NEC</b>		
Skin oedema	2	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	3	0
Hypersensitivity vasculitis	2	0
Vasculitic rash	12	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	24	0
<b>Urticarias</b>		



# Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Chronic spontaneous urticaria	2	0
Cold urticaria	2	0
Idiopathic urticaria	4	0
Urticaria	1275	0
Urticaria chronic	10	0
Urticaria papular	1	0
Urticaria thermal	5	0
Urticarial vasculitis	5	0
<b>Skin disorders SOC TOTAL</b>	<b>28397</b>	<b>1</b>

## Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Childhood	1	0
Menarche	1	0
Menopause	2	0
<i><b>Bereavement issues</b></i>		
Death of relative	1	1
<i><b>Criminal activity</b></i>		
Chemical submission	1	0
<i><b>Dietary and nutritional issues</b></i>		
Inadequate diet	1	0
<i><b>Disability issues</b></i>		
Bedridden	48	0
Dependence on oxygen therapy	1	0
Disability	1	0
Hearing disability	1	0
Immobile	21	0
Immobilisation prolonged	1	0
Impaired driving ability	2	0
Impaired work ability	5	0
Loss of personal independence in daily activities	2	0
Sight disability	11	0
Sitting disability	1	0
Walking disability	2	0
<i><b>Employment issues</b></i>		
Retirement	3	0
Stress at work	1	0
<i><b>Family and partner issues</b></i>		
Homosexual parent	1	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Food contamination	1	0
Water pollution	1	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	4	0
<i><b>Social issues NEC</b></i>		
Contraindication to medical treatment	1	0
Contraindication to vaccination	2	0
Convalescent	1	0
<i><b>Tobacco use</b></i>		
Non-tobacco user	3	0
Tobacco user	2	0
<b>Social circumstances SOC TOTAL</b>	<b>123</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<b><i>Anaesthesia and allied procedures</i></b>		
Local anaesthesia	2	0
Nerve block	1	0
<b><i>Analgesia supportive care</i></b>		
Analgesic therapy	1	0
<b><i>Antiinfective therapies</i></b>		
COVID-19 treatment	4	0
<b><i>Blood and blood product treatment</i></b>		
Photopheresis	1	0
<b><i>Breast therapeutic procedures NEC</i></b>		
Axillary lymphadenectomy	1	0
<b><i>Bronchial and pulmonary therapeutic procedures</i></b>		
Airway secretion clearance therapy	1	0
<b><i>Cardiac device therapeutic procedures</i></b>		
Pacemaker generated rhythm	1	0
<b><i>Cardiac therapeutic procedures NEC</i></b>		
Pericardial excision	1	0
<b><i>Contraceptive methods female</i></b>		
Contraceptive diaphragm	2	0
<b><i>Dietary and nutritional therapies</i></b>		
Fluid replacement	1	0
Medical diet	1	0
Nothing by mouth order	1	0
<b><i>External ear therapeutic procedures</i></b>		
Cerumen removal	1	0
<b><i>Eye therapeutic procedures NEC</i></b>		
Eye irrigation	2	0
<b><i>Facial therapeutic procedures</i></b>		
Face lift	2	0
<b><i>Fertility and fertilisation interventions female</i></b>		
Ovulation induction	1	0
<b><i>Gastrointestinal therapeutic procedures NEC</i></b>		
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	22	0
<b><i>Haematological therapeutic procedures NEC</i></b>		
Anticoagulant therapy	1	0
<b><i>Head, neck and oral cavity therapeutic procedures NEC</i></b>		
Neck lift	1	0
<b><i>Hormonal therapeutic procedures NEC</i></b>		
Hormone replacement therapy	3	0
<b><i>Immunisations</i></b>		
COVID-19 immunisation	124	1
Immunisation	58	0
<b><i>Induced abortions</i></b>		
Abortion induced	1	0
<b><i>Joint therapeutic procedures</i></b>		
Hip surgery	1	0
Joint injection	1	0
<b><i>Large intestine therapeutic procedures</i></b>		
Appendectomy	2	0
<b><i>Limb therapeutic procedures</i></b>		
Limb immobilisation	18	0
Limb operation	4	0

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
Limb reattachment surgery	1	0
Toe amputation	1	0
<b>Mastectomies</b>		
Breast conserving surgery	1	0
<b>Muscle therapeutic procedures</b>		
Muscle relaxant therapy	1	0
<b>Nasal therapeutic procedures</b>		
Nasal irrigation	1	0
<b>Nervous system therapeutic procedures NEC</b>		
Central nervous system stimulation	2	0
<b>Orbit and globe therapeutic procedures</b>		
Eye muscle operation	1	0
<b>Patient positioning</b>		
Prone position	1	0
<b>Prophylactic procedures NEC</b>		
Anaphylaxis prophylaxis	2	0
<b>Skin and subcutaneous tissue therapeutic procedures NEC</b>		
Dermal filler injection	1	0
<b>Small intestine therapeutic procedures</b>		
Ileostomy	2	0
<b>Spine and spinal cord therapeutic procedures</b>		
Spinal operation	1	0
<b>Testicular and scrotal therapeutic procedures</b>		
Testes exploration	1	0
<b>Therapeutic procedures NEC</b>		
Anaphylaxis treatment	3	0
Bed rest	18	0
Catheter management	1	0
Catheter placement	1	0
Fatigue management	1	0
Hospitalisation	6	0
Injection	29	0
Localised alternating hot and cold therapy	5	0
Manipulation	1	0
Mass excision	6	0
Product used for unknown indication	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Stoma care	1	0
Surgery	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0
<b>Uterine therapeutic procedures</b>		
Endometrial ablation	1	0
<b>Vascular therapeutic procedures NEC</b>		
Thrombectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>359</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive crisis	5	0
Hypertensive emergency	1	0
Hypertensive urgency	1	0
Malignant hypertension	1	0
Tyramine reaction	1	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Aneurysm	3	1
Artery dissection	1	0
<b><i>Aortic aneurysms and dissections</i></b>		
Aortic aneurysm	3	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	7	0
Aortic thrombosis	2	1
<b><i>Aortic infections and inflammations</i></b>		
Aortitis	1	0
<b><i>Arterial infections and inflammations</i></b>		
Arteritis	1	0
Giant cell arteritis	21	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	8	0
Labile blood pressure	1	0
<b><i>Bruising, ecchymosis and purpura</i></b>		
Achenbach syndrome	1	0
<b><i>Circulatory collapse and shock</i></b>		
Circulatory collapse	53	1
Distributive shock	1	0
Neurogenic shock	8	0
Peripheral circulatory failure	2	0
Shock	31	0
Shock symptom	4	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	5	0
Haematoma	41	0
Haemorrhage	149	2
Internal haemorrhage	3	0
Venous haemorrhage	1	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	35	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Arterial thrombosis	4	1
Embolism	39	1
Embolism venous	6	0
Microembolism	1	0
Thrombophlebitis migrans	1	0
Thrombosis	399	17
Venous thrombosis	10	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Arterial occlusive disease	1	0
Arterial spasm	1	0
Arteriosclerosis	1	0
Haemorrhagic infarction	1	0
Infarction	1	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Ischaemia	1	0
Peripheral venous disease	3	0
Vasospasm	3	0
<b>Non-site specific vascular disorders NEC</b>		
Capillary fragility	1	0
Haemodynamic instability	1	0
Neovascularisation	1	0
Vascular pain	35	0
Vascular rupture	1	0
Vasodilatation	41	0
Vein discolouration	1	0
Vein disorder	1	0
Vein rupture	3	0
<b>Peripheral embolism and thrombosis</b>		
Blue toe syndrome	11	0
Deep vein thrombosis	302	3
Iliac artery embolism	1	0
Jugular vein thrombosis	4	0
Pelvic venous thrombosis	3	0
Peripheral artery thrombosis	5	0
Peripheral embolism	2	0
Thrombophlebitis	33	0
Thrombophlebitis superficial	13	0
Venous thrombosis limb	2	0
<b>Peripheral vascular disorders NEC</b>		
Cyanosis	60	0
Erythromelalgia	2	0
Flushing	486	0
Hot flush	1331	0
Peripheral vascular disorder	2	0
<b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b>		
Extremity necrosis	1	0
Intermittent claudication	2	0
Ischaemic limb pain	3	0
Peripheral artery occlusion	2	0
Peripheral coldness	812	0
Peripheral ischaemia	2	0
Poor peripheral circulation	18	0
Raynaud's phenomenon	62	0
<b>Phlebitis NEC</b>		
Phlebitis	18	0
Phlebitis superficial	2	0
<b>Site specific vascular disorders NEC</b>		
Pallor	271	0
Plethoric face	1	0
<b>Varicose veins NEC</b>		
Spider vein	2	0
Varicophlebitis	2	0
Varicose vein	28	0
<b>Vascular hypertensive disorders NEC</b>		
Diastolic hypertension	1	0
Hypertension	357	0
Labile hypertension	1	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Systolic hypertension	2	0
White coat hypertension	4	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	3	0
Hypotension	297	0
Orthostatic hypotension	25	0
<b><i>Vasculitides NEC</i></b>		
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	27	0
<b><i>Vena caval embolism and thrombosis</i></b>		
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>5153</b>	<b>29</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>492105</b>	<b>521</b>
<b>TOTAL REPORTS</b>	<b>129673</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>521</b>