COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 28-May-2021

Data Lock Date: 26-May-2021 19:00:03

All UK spontaneous reports received between 4/01/21 and 26/05/2021 for COVID-19 vaccine Oxford University/AstraZeneca.

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

Case Series Drug Analysis Print Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 28-May-2021 Data Lock Date: 26-May-2021 19:00:03
Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name	Tota	L,	Fatal
Blood disorders			
Anaemia deficiencies			
Anaemia vitamin B12 deficiency		6	0
Iron deficiency anaemia		6	0
Pernicious anaemia		1	0
Anaemias NEC			
Anaemia		68	0
Blood loss anaemia		2	0
Microcytic anaemia		1	0
Normocytic anaemia		1	0
Anaemias haemolytic NEC			
Haemolytic anaemia		8	0
Anaemias haemolytic immune			
Autoimmune haemolytic anaemia		3	0
Anaemias haemolytic mechanical factor			
Atypical haemolytic uraemic syndrome		1	0
Red cell fragmentation syndrome		1	0
Bleeding tendencies			
Increased tendency to bruise		34	0
Spontaneous haematoma		5	0
Spontaneous haemorrhage		1	0
Coagulation factor deficiencies			
Hypofibrinogenaemia		4	0
Coagulopathies			
Abnormal clotting factor		7	0
Antiphospholipid syndrome		22	0
Coagulopathy		40	0
Disseminated intravascular coagulation		15	1
Hypercoagulation		18	1
Eosinophilic disorders			
Eosinophilia		16	0
Hypereosinophilic syndrome		1	0
Haematological disorders			J
Blood disorder		6	0
Bone marrow disorder		2	0
Bone marrow oedema		1	0
Mast cell activation syndrome		5	0
Mastocytosis		1	Ö
Methaemoglobinaemia		1	0
Haemolyses NEC		İ	
Haemolysis		8	0
Leukocytoses NEC			
Leukocytosis		3	0
Lymphocytosis		7	Ö
Monocytosis		2	0
Neutrophilia		13	0
Leukopenias NEC			J
Leukopenia		8	0
Lymphopenia		8	0
Lymphatic system disorders NEC			- 0
Abdominal lymphadenopathy		1	0
Lymph node fibrosis		1	0
Lymph node pain	A1	30	0
Lymphadenitis		25	0

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Reaction Name MedDRA Version: MedDRA 24.0	Total	Fatal
Blood disorders Blood disorders cont'd	lotai	Гаца
Lymphadenopathy	4134	0
Lymphatic disorder	1	0
Pseudolymphoma	3	
Marrow depression and hypoplastic anaemias	٦	U
Aplastic anaemia	1	0
Myelosuppression	3	0
Pancytopenia	14	0
Neutropenias	14	U
Agranulocytosis	1	0
Autoimmune neutropenia	2	0
Febrile neutropenia	1	0
Neutropenia	69	0
Platelet disorders NEC	09	U
Platelet anisocytosis	3	0
Platelet disorder	4	0
Polycythaemia (excl rubra vera)	4	U
Stress polycythaemia	2	0
Purpuras (excl thrombocytopenic)		U
Purpura non-thrombocytopenic	4	0
Red blood cell abnormal findings NEC	4	U
Anisocytosis	1	0
Macrocytosis	1	0
Poikilocytosis	2	0
Polychromasia	3	0
Sickle cell trait and disorders	٥	U
Sickle cell anaemia with crisis	5	0
Spleen disorders	٦	U
Spleen disorder	1	0
Splenic artery thrombosis	2	0
Splenic haemorrhage	1	0
Splenic infarction	10	
Splenic thrombosis	10	0
Splenic varices	1	0
Splenic varices Splenic vein thrombosis	9	0
Splenomegaly	5	
Thrombocytopenias]	U
Autoimmune heparin-induced thrombocytopenia	1	0
Heparin-induced thrombocytopenia	10	0
Immune thrombocytopenia	186	
Thrombocytopenia	680	
Thrombocytopenia Thrombocytopenic purpura	8	5 0
Thrombocytopenic purpura	1	0
Thrombocytoses		
	8	0
Thrombocytosis		0
White blood cell abnormal findings NEC	2	^
White blood cell disorder	3	0 8
Blood disorders SOC TOTAL	6067	

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Reaction NameTotalCardiac disordersAortic valvular disordersAortic valve incompetence1Aortic valve stenosis1Cardiac conduction disorders1Atrioventricular block14Atrioventricular block complete3Atrioventricular block first degree1Atrioventricular block second degree3Brugada syndrome1Bundle branch block1Bundle branch block left6Bundle branch block right2	0 0
Aortic valvular disorders1Aortic valve incompetence1Aortic valve stenosis1Cardiac conduction disorders14Atrioventricular block14Atrioventricular block complete3Atrioventricular block first degree1Atrioventricular block second degree3Brugada syndrome1Bundle branch block1Bundle branch block left6	0
Aortic valve incompetence 1 Aortic valve stenosis 1 Cardiac conduction disorders Atrioventricular block 14 Atrioventricular block complete 3 Atrioventricular block first degree 1 Atrioventricular block second degree 3 Brugada syndrome 1 Bundle branch block left 6	0
Aortic valve stenosis Cardiac conduction disorders Atrioventricular block Atrioventricular block complete Atrioventricular block first degree Atrioventricular block second degree Brugada syndrome Bundle branch block Bundle branch block left	0
Aortic valve stenosis Cardiac conduction disorders Atrioventricular block Atrioventricular block complete Atrioventricular block first degree Atrioventricular block second degree Brugada syndrome Bundle branch block Bundle branch block left	0
Cardiac conduction disordersAtrioventricular block14Atrioventricular block complete3Atrioventricular block first degree1Atrioventricular block second degree3Brugada syndrome1Bundle branch block1Bundle branch block left6	
Atrioventricular block 14 Atrioventricular block complete 3 Atrioventricular block first degree 1 Atrioventricular block second degree 3 Brugada syndrome 1 Bundle branch block 1 Bundle branch block left 6	
Atrioventricular block complete 3 Atrioventricular block first degree 1 Atrioventricular block second degree 3 Brugada syndrome 1 Bundle branch block 1 Bundle branch block left 6	0
Atrioventricular block first degree 1 Atrioventricular block second degree 3 Brugada syndrome 1 Bundle branch block 1 Bundle branch block left 6	0
Atrioventricular block second degree 3 Brugada syndrome 1 Bundle branch block 1 Bundle branch block left 6	0
Brugada syndrome 1 Bundle branch block 1 Bundle branch block left 6	0
Bundle branch block 1 Bundle branch block left 6	0
Bundle branch block left 6	0
	0
Duritie branch block right 2	0
Long OT ayadromo	_
Long QT syndrome 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	0
	0
Cardiac disorders NEC	^
Acute cardiac event 4	2
Atrial thrombosis 2	0
Cardiac disorder 46	0
Cardiac dysfunction 1	0
Cardiac ventricular thrombosis 6	2
Cardiovascular disorder 6	1
Cardiovascular insufficiency 10	0
Intracardiac thrombus 3	0
Cardiac hypertensive complications	
Hypertensive heart disease 1	0
Cardiac infections and inflammations NEC	
Carditis 1	0
Cardiac signs and symptoms NEC	
Cardiac discomfort 11	0
Cardiovascular symptom 1	0
Palpitations 4226	0
Cardiac valve disorders NEC	
Cardiac valve disease 1	1
Heart valve incompetence 1	0
Cardiomyopathies	
Cardiomyopathy 8	1
Congestive cardiomyopathy 7	0
Stress cardiomyopathy 2	0
Coronary artery disorders NEC	
Arteriosclerosis coronary artery	0
Coronary artery disease 6	0
Coronary artery dissection 1	0
Coronary artery embolism 1	0
Coronary artery occlusion 1	0
Coronary artery thrombosis	2
Heart failures NEC	
Cardiac failure 46	6
Cardiac failure acute 5	0
Cardiac failure congestive	1
Cardiogenic shock 6	2
Cardiopulmonary failure 1	1
Ischaemic coronary artery disorders	
Acute coronary syndrome 6	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute myocardial infarction	47	7 7
Angina pectoris	147	r 0
Angina unstable	13	sl ol
Arteriospasm coronary		
Microvascular coronary artery disease	2	el ol
Myocardial infarction	257	36
Myocardial ischaemia	19	
Prinzmetal angina		
Left ventricular failures		
Acute left ventricular failure	4	ıl ol
Left ventricular failure		_
Mitral valvular disorders	2	-
Mitral valve incompetence	5	5 0
Mitral valve prolapse		ا ا
Myocardial disorders NEC		il i
Cardiomegaly	11	ا
Diastolic dysfunction		
Left atrial dilatation		
Left ventricular dilatation	2	_
		-
Left ventricular dysfunction	11	
Left ventricular hypertrophy		0
Myocardial rupture		0
Right ventricular dilatation		0
Right ventricular dysfunction	3	
Ventricular hypertrophy	3	3 1
Noninfectious myocarditis		
Myocarditis	30) 1
Noninfectious pericarditis		
Pericarditis	51	0
Pericardial disorders NEC		
Cardiac tamponade	1	1
Pericardial effusion	15	
Pericardial haemorrhage	4	
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	94	
Bradycardia	58	3 0
Cardiac fibrillation	2	
Cardiac flutter	162	
Extrasystoles	101	0
Heart alternation	3	3 0
Paroxysmal arrhythmia	2	의 이
Postural orthostatic tachycardia syndrome	g	9 o
Tachyarrhythmia	10	
Tachycardia	1116	6 0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	2	
Supraventricular arrhythmias		
Arrhythmia supraventricular	13	3 0
Atrial fibrillation	232	
Atrial flutter	25	
Atrial tachycardia		

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	2	0
Sinus node dysfunction	1	0
Sinus tachycardia	59	1
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	24	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	4	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	129	31
Cardio-respiratory arrest	2	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	5	0
Ventricular fibrillation	5	0
Ventricular tachycardia	12	0
Cardiac disorders SOC TOTAL	7177	110

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	RA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Congenital disorders		
Arterial disorders congenital		
Congenital arterial malformation	1	0
Autosomal chromosomal abnormalities		
Trisomy 21	1	0
Cardiac disorders congenital NEC		
Heart disease congenital	10) 0
Cardiac septal defects congenital		
Hypertrophic cardiomyopathy	6	6 0
Ventricular septal defect	1	0
Cardiovascular disorders congenital NEC		
Congenital cardiovascular anomaly	1	0
Central nervous system disorders congenital NEC		
Encephalocele	3	3 0
Neural tube defect	1	1
Syringomyelia	2	2 0
Cerebellar disorders congenital		
Arnold-Chiari malformation	3	3 0
Cerebral disorders congenital		
Anencephaly	1	0
Cerebral palsy	6	6 0
Congenital hydrocephalus	1	ıl ol
Coagulation disorders congenital		
Haemophilia	2	<u>2</u> 0
Protein C deficiency	3	
Protein S deficiency	1	ıl ol
Congenital disorders NEC		
Foetal malformation	1	ıl ol
Young's syndrome	3	3 0
Connective tissue disorders congenital		
Ehlers-Danlos syndrome	6	6 0
Gastric disorders congenital		
Pyloric stenosis	1	0
Great vessel disorders congenital		
Coarctation of the aorta	1	0
Transposition of the great vessels	3	3 0
Haematological disorders congenital NEC		
Neonatal alloimmune thrombocytopenia	1	0
Haemoglobinopathies congenital		
Sickle cell trait	1	0
Immune system abnormalities congenital		
Combined immunodeficiency	1	0
Inborn errors of porphyrin metabolism		
Porphyria	1	0
Porphyria acute	1	0
Lymphatic system disorders congenital		
Cystic lymphangioma	1	ıl ol
Lysosomal storage disorders		
Mucolipidosis	1	ıl ol
Male reproductive tract disorders congenital		
Cryptorchism	1	0
Hydrocele	1	il ől
Micropenis	2	
Penoscrotal fusion	2	

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Musculoskeletal and connective tissue disorders of limbs congenital		
Congenital hand malformation	1	0
Limb reduction defect	1	0
Polydactyly	1	0
Musculoskeletal disorders congenital NEC		
Congenital multiplex arthrogryposis	1	0
Dysmorphism	1	0
Otopalatodigital spectrum disorder	1	0
Neurological disorders congenital NEC		
Epilepsy with myoclonic-atonic seizures	1	0
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
Spinal muscular atrophy	1	0
Tourette's disorder	1	0
Non-site specific muscle disorders congenital		
Muscular dystrophy	2	0
Ocular disorders congenital NEC		
Colour blindness	1	0
Pancreatic disorders congenital		
Hereditary pancreatitis	1	0
Peripheral nervous system disorders congenital NEC		
Paroxysmal extreme pain disorder	11	0
Pulmonary and bronchial disorders congenital		
Cystic fibrosis	4	0
Renal disorders congenital		
Congenital cystic kidney disease	1	0
Sex chromosomal abnormalities		
Klinefelter's syndrome	1	0
Vascular anomalies congenital NEC		
Arteriovenous malformation	1	0
Klippel-Trenaunay syndrome	2	0
Congenital disorders SOC TOTAL	106	1

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Reaction Name	Total	<u> Fatal</u>
Ear disorders		
Ear disorders NEC		
Ear congestion	23	3 0
Ear discomfort	83	3 0
Ear disorder	10	0 (
Ear haemorrhage	10	1
Ear pain	1713	
Ear pruritus		1 0
Ear swelling	58	
Otorrhoea		0
Paraesthesia ear		il o
Eustachian tube disorders		
Eustachian tube disorder	3	3 0
Eustachian tube dysfunction		i ő
Eustachian tube obstruction		
External ear disorders NEC		Ï
Excessive cerumen production	25	5 0
External ear pain	1	
Red ear syndrome		5 0
External ear infections and inflammations		1
External ear inflammation		2 0
Hearing disorders NEC	4	
Auditory disorder		ıl o
Hearing losses		
Deafness	247	7 0
Deafness bilateral	10	
Deafness bilateral Deafness neurosensory	17	
Deafness transitory		3 0
Deafness transitory Deafness unilateral	38	
Hypoacusis	15	
	13,	
Neurosensory hypoacusis	44	
Sudden hearing loss	44	+
Hyperacusia	103	
Hyperacusis Inner ear disorders NEC	100	0
Inner ear disorder	2	
Meniere's disease Vestibular disorder		
Inner ear infections and inflammations	·	5 0
Autoimmune inner ear disease		
		0 0
Inner ear inflammation		1 0
Inner ear signs and symptoms	0.	
Motion sickness	94	1 0
Phobic postural vertigo	20.44	
Tinnitus	2842	
Vertigo	1563	
Vertigo labyrinthine	9	
Vertigo positional	94	1 0
Middle ear disorders NEC		_
Middle ear disorder		0
Middle ear effusion		3 0
Tympanic membrane disorders (excl infections)		
Tympanic membrane perforation	4	1 0
Ear disorders SOC TOTAL	7222	2 0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA	A 24.0	
Reaction Name	<u>Total</u>	<u>Fatal</u>
Endocrine disorders		
Acute and chronic thyroiditis		
Autoimmune thyroiditis	3	0
Thyroiditis	8	0
Thyroiditis acute	4	0
Thyroiditis chronic	1	0
Thyroiditis subacute	1	0
Adrenal cortical hyperfunctions		
Cushing's syndrome	1	0
Cushingoid	5	0
Adrenal cortical hypofunctions		
Addison's disease	2	0
Adrenal insufficiency	15	0
Adrenocortical insufficiency acute	28	0
Glucocorticoid deficiency	1	0
Secondary adrenocortical insufficiency	1	0
Adrenal gland disorders NEC		
Adrenal disorder	1	0
Adrenal haemorrhage	7	0
Adrenal mass	1	0
Adrenal thrombosis	1	0
Adrenomegaly	1	0
Haemorrhagic adrenal infarction	2	0
Anterior pituitary hypofunction		
Hypopituitarism	2	0
Ectopic endocrine disorders		
Carcinoid syndrome	1	0
Endocrine abnormalities of puberty		
Delayed menarche	1	0
Premature menarche	6	0
Female gonadal function disorders		
Anovulatory cycle	7	0
Ovulation delayed	6	0
Hyperparathyroid disorders		
Hyperparathyroidism	1	0
Hypoparathyroid disorders		
Hypoparathyroidism	3	0
Hypothalamic and pituitary disorders NEC		
Pituitary apoplexy	1	0
Posterior pituitary disorders		
Diabetes insipidus	5	0
Inappropriate antidiuretic hormone secretion	1	0
Thyroid disorders NEC		
Goitre	12	0
Thyroid disorder	10	0
Thyroid mass	3	0
Thyroid pain	10	0
Thyroid hyperfunction disorders		
Basedow's disease	4	0
Hyperthyroidism	24	
Thyrotoxic crisis	2	0
Thyroid hypofunction disorders		
Hypothyroidism	36	0
Endocrine disorders SOC TOTAL	218	

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Eye disorders		
Amblyopic vision impairment		
Amblyopia	3	0
Cataract conditions		
Cataract	12	0
Cataract cortical	2	0
Cataract subcapsular	3	0
Choroid and vitreous haemorrhages and vascular disorders		
Vitreous haemorrhage	5	0
Choroid and vitreous structural change, deposit and degeneration		
Chorioretinopathy	3	0
Vitreous detachment	38	0
Vitreous floaters	127	0
Vitreous opacities	1	0
Colour blindness (incl acquired)	·	Ŭ
Dyschromatopsia	15	0
Conjunctival and corneal bleeding and vascular disorders	١٠	
Conjunctival haemorrhage	103	0
Conjunctival infections, irritations and inflammations	103	J
Conjunctival hyperaemia	1	0
Corneal infections, oedemas and inflammations	1	U
Keratitis	2	0
Ulcerative keratitis	2	0
		U
Corneal structural change, deposit and degeneration	1	^
Corneal perforation	1	0
Eyelid movement disorders	00	^
Blepharospasm	99	0
Excessive eye blinking	6	0
Eyelid ptosis	35	U
Glaucomas (excl congenital)		^
Angle closure glaucoma	2 5	0
Glaucoma) 1	0
Ocular hypertension	I	U
Iris and ciliary body structural change, deposit and degeneration		^
Eye colour change	6	0
Iris and uveal tract infections, irritations and inflammations		^
Autoimmune uveitis	1 47	0
Iridocyclitis	17	0
Iritis	9	0
Uveitis	28	0
Lacrimation disorders	0.40	_
Dry eye	242	
Lacrimation increased	204	0
Lens structural change, deposit and degeneration (excl cataracts)	_	•
Anterior capsule contraction	1	0
Lid bleeding and vascular disorders		_
Eyelid bleeding	2	0
Eyelid haematoma	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	15	0
Chalazion	2	0
Eczema eyelids	2	0
Erythema of eyelid	5	0
Eyelid cyst	11	0

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Reaction Name	Total	<u> Fatal</u>
Eye disorders Eye disorders cont'd		
Eyelid irritation		3 0
Eyelid margin crusting		1l ol
Eyelid oedema	1	1l ol
Eyelid rash	1	
Swelling of eyelid	10	
Lid, lash and lacrimal structural disorders	10	'l
Eyelid exfoliation		2 0
1		اء اء
Eyelid skin dryness Eyelid thickening		_ _
, ,		
Growth of eyelashes		5 0 2 0
Lagophthalmos		2 0
Ocular bleeding and vascular disorders NE		
Eye haematoma		3 0
Eye haemorrhage	7.	
Ocular vascular disorder		1 0
Ophthalmic vein thrombosis		3 0
Ocular cysts and polyps		
Vitreous cyst		1 0
Ocular disorders NEC		
Dark circles under eyes		6 0
Eye disorder	1	
Eye oedema	1.	
Eye pain	292	
Eye swelling	49	5 0
Eye symptom		9 0
Eye ulcer		9 0
Eyelid disorder		5 0
Eyelid pain	1	6l ol
Eyelids pruritus		7l ol
Ocular discomfort	5	5l ol
Periorbital oedema	1	
Periorbital pain		3 0
Periorbital swelling	8	
Retinal disorder		1 0
Ocular infections, inflammations and associ	ciated manifestations	
Autoimmune eye disorder		1 0
Eye allergy	2	
Eye discharge	2	
Eye inflammation	2	
Eye irritation	17	
Eye pruritus	25	
Limbal swelling		6 0
Ocular hyperaemia	34	
Ocular riyperaerilla Ocular rosacea	34	1 0
Ocular nerve and muscle disorders		1 9
		ا ا
Extraocular muscle paresis		8 0
Eye movement disorder	3	I I
Gaze palsy		3 0
Ocular myasthenia		2 0
Ophthalmoplegia		1 0
Strabismus		4 0
Ocular sensation disorders		
Abnormal sensation in eye	2	1 0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Asthenopia	301	0
Eye paraesthesia	4	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	33	0
Hypoaesthesia eye	24	0
Photophobia	883	0
Optic disc abnormalities NEC		
Optic atrophy	1	0
Optic discs blurred	2	0
Papilloedema	9	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	5	0
Orbital structural change, deposit and degeneration	Ŭ	J
Lid sulcus deepened	3	0
Pupil disorders	Ŭ	Ŭ
Miosis	10	0
Mydriasis	27	0
Pupil fixed	9	0
Pupils unequal	9	0
Refractive and accommodative disorders	Ĭ	
Altered visual depth perception	4	0
Hypermetropia	1	0
Refraction disorder	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal aneurysm	1	0
Retinal artery embolism	2	0
Retinal artery occlusion	16	
Retinal haemorrhage	10	0
Retinal infarction	1	0
Retinal vascular occlusion	1	0
Retinal vascular thrombosis	2	0
Retinal vein occlusion	49	0
Retinal vein thrombosis	5	0
Retinal vein varices	1	0
Retinal structural change, deposit and degeneration		
Macular cyst	1	0
Macular degeneration	5	0
Macular detachment	1	0
Macular hole	2	0
Neovascular age-related macular degeneration	10	0
Retinal detachment	18	0
Retinal drusen	1	0
Retinal tear	10	0
Retinal toxicity	2	0
Vitreoretinal traction syndrome	1	0
Retinal, choroid and vitreous infections and inflammations		
Macular oedema	4	0
Retinopathies NEC		
Acute macular outer retinopathy	4	0
Acute zonal occult outer retinopathy	1	0
Retinal exudates	13	
Retinopathy	6	

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Reaction Name	Total_	Fatal
Eye disorders Eye disorders cont'd		
Scleral infections, irritations and inflammations		
Episcleritis	13	0
Scleritis	6	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	1	0
Structural change, deposit and degeneration of eye NEC		
Deposit eye	1	0
Endocrine ophthalmopathy	2	0
Exophthalmos	4	0
Visual colour distortions		
Chloropsia	1	0
Chromatopsia	1	0
Cyanopsia	1	0
Erythropsia	3	0
Xanthopsia	7	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Diplopia	250	0
Dysmetropsia	1	0
Halo vision	10	0
Metamorphopsia	27	0
Photopsia	256	
Scintillating scotoma	5	0
Vision blurred	2187	0
Visual brightness	8	0
Visual snow syndrome	3	0
Visual field disorders		
Visual field defect	23	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	6	0
Blindness	209	
Blindness transient	17	0
Blindness unilateral	21	0
Central vision loss	2	0
Night blindness	4	
Sudden visual loss	4	0
Visual acuity reduced	25	0
Visual acuity reduced transiently	1	0
Visual impairment	526	0
Visual impairment Visual pathway disorders	320	U
Optic nerve disorder	1	0
Optic neuropathy	4	
	10948	0
Eye disorders SOC TOTAL	1 10948	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Gastrointestinal disorders		
Abdominal findings abnormal		
Abdominal mass		8 0
Gastrointestinal sounds abnormal	16	6 0
Acute and chronic pancreatitis		
Obstructive pancreatitis	1	1
Pancreatitis	28	3 1
Pancreatitis acute	14	· 0
Pancreatitis chronic	1	0
Anal and rectal disorders NEC		
Anal fissure	2	2 0
Anal and rectal pains		
Proctalgia	25	5 0
Anal and rectal signs and symptoms		
Anal blister	2	2 0
Anal hypoaesthesia		· 0
Anal inflammation	1	0
Anal paraesthesia	1	0
Anal pruritus		· 0
Anal spasm	1	0
Anorectal discomfort		· 0
Anorectal swelling	1	0
Rectal discharge	1	0
Benign oral cavity neoplasms		
Mouth cyst	12	2 0
Tongue cyst	5	5 0
Tongue polyp	2	2 0
Colitis (excl infective)		
Autoimmune colitis	2	2 0
Colitis	38	8 0
Colitis ischaemic	5	5 1
Colitis microscopic	3	8 0
Colitis ulcerative	68	8 0
Crohn's disease	63	8 0
Inflammatory bowel disease	8	8 0
Terminal ileitis	1	0
Dental and periodontal infections and inflamr	nations	
Dental caries	3	8 0
Dental disorders NEC		
Diastema	1	0
Loose tooth	1	0
Malpositioned teeth	1	0
Teething	19	0
Tooth disorder	2	2 0
Tooth socket haemorrhage	2	2 0
Dental pain and sensation disorders		
Dental discomfort	11	0
Dental paraesthesia	16	6 0
Hyperaesthesia teeth	44	↓ o
Hypoaesthesia teeth		2 0
Toothache	269	o o
Dental pulp disorders		
Dental pulp disorder		0
Dental surface disorders		

	DRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders cont'd		
Tooth discolouration	13	0
Diaphragmatic hernias		
Hiatus hernia	9	0
Diarrhoea (excl infective)		
Diarrhoea	7635	6 0
Diarrhoea haemorrhagic	27	0
Diverticula		
Diverticulum	9	0
Duodenal and small intestinal stenosis and obstru	ection	
Small intestinal obstruction	1	0
Superior mesenteric artery syndrome	1	0
Duodenal ulcers and perforation		
Duodenal ulcer	1	0
Duodenal ulcer haemorrhage	2	2 1
Dyspeptic signs and symptoms		
Dyspepsia	720	
Epigastric discomfort	16	
Eructation	81	0
Faecal abnormalities NEC		
Abnormal faeces	14	
Faecaloma	2	
Faeces discoloured	42	
Faeces hard	4	
Faeces pale	6	
Faeces soft	18	
Mucous stools	11	0
Flatulence, bloating and distension		
Abdominal distension	408	
Flatulence	348	0
Gastric and oesophageal haemorrhages	_	
Gastric haemorrhage	7	7 0
Gastric ulcers and perforation		
Gastric ulcer	9	
Gastric ulcer haemorrhage		
Gastric ulcer perforation	1	0
Gastritis (excl infective)		
Chronic gastritis	3	
Gastritis	67	
Reflux gastritis	15	0
Gastrointestinal and abdominal pains (excl oral at		
Abdominal migraine	3004	
Abdominal pain	3831	
Abdominal pain lower	192	
Abdominal pain upper	4380	
Abdominal rigidity	48	1
Abdominal tenderness	17	
Gastrointestinal pain	269	
Oesophageal pain	NEC 6	0
Gastrointestinal atonic and hypomotility disorders		,
Constipation	367	
Duodenogastric reflux Gastric dilatation	2	
-	14	
Gastrooesophageal reflux disease	171	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Gastrointestinal disorders co	nt'd		
Impaired gastric emptying		4	0
Infrequent bowel movements		3	0
Intestinal dilatation		1	0
Gastrointestinal disorders NEC			
Appendix disorder		1	0
Food poisoning		11	0
Functional gastrointestinal disorder		9	0
Gastric disorder		8	0
Gastrointestinal disorder		22	0
Gastrointestinal oedema		3	0
Gastroptosis		1	0
Neurogenic bowel		1	0
Gastrointestinal dyskinetic disorders			_
Bowel movement irregularity		3	0
Change of bowel habit		14	0
Defaecation disorder		1	0
Dyschezia		13	0
Gastrointestinal motility disorder		2	0
Oesophageal achalasia		2	0
Gastrointestinal inflammatory disorders NEC		_	Ŭ
Appendicitis noninfective		2	0
Enteritis		1	0
Gastrointestinal inflammation		1	0
Gastrointestinal tract irritation		4	0
Intestinal angioedema		1	0
Ischaemic enteritis		1	0
Gastrointestinal mucosal dystrophies and se	cretion disorders		J
Achlorhydria	oronom alcordoro	1	0
Hyperchlorhydria		2	0
Gastrointestinal necrosis and gangrene (exc	gangrenous hernia)	_	ŭ
Gastrointestinal necrosis	gangreneae nermaj	1	0
Gastrointestinal signs and symptoms NEC			ŭ
Abdominal discomfort		1369	0
Abdominal symptom		5	0
Acute abdomen		13	0
Anal incontinence		34	0
Breath odour		21	0
Dysphagia		192	0
Intestinal congestion		1	0
Odynophagia		25	0
Gastrointestinal spastic and hypermotility dis	orders		_
Cardiospasm		2	1
Defaecation urgency		12	0
Frequent bowel movements		37	0
Irritable bowel syndrome		98	0
Oesophageal spasm		6	0
Gastrointestinal stenosis and obstruction NE	C		_
Intestinal obstruction		4	0
Intussusception		1	0
Volvulus		1	1
Gastrointestinal ulcers and perforation, site u	Inspecified		
Gastrointestinal perforation	,	1	0
Gastrointestinal vascular malformations			

	/ersion: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Gastrointestinal disorders cont'd		
Gastric antral vascular ectasia	6	0
Gastrointestinal vascular occlusion and infarction		
Intestinal infarction	3	
Intestinal ischaemia	22	2 1
Mesenteric artery embolism	1	
Mesenteric artery thrombosis	2	
Mesenteric vein thrombosis	14	0
Mesenteric venous occlusion	1	
Thrombosis mesenteric vessel	3	
Visceral venous thrombosis	10	1
Gingival disorders, signs and symptoms NEC		
Epulis		0
Gingival blister	21	0
Gingival discomfort	5	0
Gingival disorder	12	2 0
Gingival hypertrophy		_
Gingival oedema	2	
Gingival pain	195	
Gingival pruritus	1	0
Gingival recession	1	0
Gingival swelling	40	0
Gingival ulceration	7	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	19	0
Gingival haemorrhages		
Gingival bleeding	114	. 0
Haemorrhoids and gastrointestinal varices (excl oesop	hageal)	
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	46	0
Haemorrhoids thrombosed	8	0
Inguinal hernias		
Inguinal hernia	3	0
Intestinal haemorrhages		
Anal haemorrhage	27	0
Intestinal haemorrhage	1	0
Lower gastrointestinal haemorrhage	2	2 0
Mesenteric haemorrhage	1	0
Rectal haemorrhage	82	
Small intestinal haemorrhage	25	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	3	0
Large intestine perforation		0
Large intestinal stenosis and obstruction		
Large intestinal obstruction		0
Large intestinal stenosis	1	0
Malabsorption syndromes		
Bile acid malabsorption	1	0
Coeliac disease	14	0
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Acetonaemic vomiting	1	0
Discoloured vomit	17	
Faecal vomiting	2	

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Reaction Name		<u>Total</u>	<u>Fatal</u>
Gastrointestinal disorders con	t'd		
Infantile vomiting		2	0
Nausea		30216	0
Regurgitation		2	0
Retching		210	0
Vomiting		10105	3
Vomiting projectile		138	0
Non-site specific gastrointestinal haemorrhage	es		•
Gastrointestinal haemorrhage	-	23	0
Haematemesis		66	0
Haematochezia		69	0
Melaena		6	0
Upper gastrointestinal haemorrhage		2	0
Oesophageal disorders NEC		-	U
Oesophageal disorder Oesophageal disorder		2	0
Oesophageal stenosis and obstruction		-	U
Oesophageal obstruction		1	0
Oesophagitis (excl infective)		'	U
		3	0
Eosinophilic oesophagitis		12	0
Oesophagitis		12	0
Oral dryness and saliva altered		4	0
Aptyalism		1030	0
Dry mouth			
Lip dry		73	0
Saliva altered		5	
Saliva discolouration		1	0
Salivary hypersecretion		68	0
Oral soft tissue disorders NEC			0
Angina bullosa haemorrhagica		10	0
Chapped lips		18	0
Cheilitis		31	0
Chronic cheek biting		1	0
Enlarged uvula		9	0
Leukoplakia oral		2	0
Lip blister		30	0
Lip disorder		3 12	0
Oral disorder			0
Oral lichen planus		8	0
Oral papule		8 2 2 5	0
Palatal disorder		2	0
Uvulitis		5	0
Oral soft tissue haemorrhages		_	
Lip haemorrhage		3	0
Mouth haemorrhage		31	0
Oral blood blister		42	0
Oral purpura		2	0
Oral soft tissue infections			
Angular cheilitis		9	0
Oral soft tissue signs and symptoms			
Anaesthesia oral		7	0
Burning mouth syndrome		11	0
Coating in mouth		3	0
Hypoaesthesia oral		523	0
Lip discolouration		1	0

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	Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Gastrointestinal disorders cont'd		
Lip erythema	4	· 0
Lip exfoliation	g	0
Lip pain	50	0
Lip pruritus	16	0
Oral discharge	1	0
Oral discomfort	76	
Oral mucosal blistering	27	' 0
Oral mucosal eruption	23	0
Oral mucosal erythema	4	· 0
Oral mucosal exfoliation	8	
Oral mucosal roughening	3	3 O
Oral pain	302	2 0
Oral pruritus	19	0
Paraesthesia oral	720	0
Oral soft tissue swelling and oedema		
Lip oedema	8	s 0
Lip swelling	814	· 0
Mouth swelling	105	5 O
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	12	
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic mass	1	0
Pancreatic steatosis	1	0
Peptic ulcers and perforation		
Peptic ulcer	1 1	0
Peritoneal and retroperitoneal disorders		
Ascites	5	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	0
Rectal inflammations NEC		
Proctitis	3	s 0
Salivary gland disorders NEC		
Salivary gland calculus	3	s 0
Salivary gland pain	11	
Salivary gland enlargements		
Parotid gland enlargement	g	o
Salivary gland enlargement	5	5 O
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	<u>2</u> 0
Stomatitis and ulceration		
Aphthous ulcer	56	6 o
Lip ulceration	14	
Mouth ulceration	639	
Stomatitis	85	
Tongue disorders		
Glossitis	15	o
Plicated tongue	4	
Tongue disorder	26	
Tongue geographic		
Tongue haemorrhage	3	Ó

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Name: COVID-19 AstraZeneca Vaccine Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disordersointestinal disorders cont'd		
Tongue ulceration	27	0
Trichoglossia	5	0
Tongue signs and symptoms		
Glossodynia	227	0
Scalloped tongue	3	0
Stiff tongue	4	0
Strawberry tongue	1	0
Swollen tongue	515	0
Tongue blistering	25	0
Tongue coated	33	0
Tongue discolouration	26	0
Tongue discomfort	40	0
Tongue dry	19	0
Tongue eruption	7	0
Tongue erythema	5	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	15	0
Tongue pruritus	3	0
Tongue rough	2	0
Tongue spasm	3	0
Tooth missing		
Tooth loss	3	0
Gastrointestinal disorders SOC TOTAL	68971	11

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site bruise	14	1 0
Administration site coldness		ı 0
Administration site erythema		6 0
Administration site extravasation		2 0
Administration site haemorrhage		ı 0
Administration site induration		ı o
Administration site mass		ı 0
Administration site pain	36	6 0
Administration site rash		2 0
Administration site reaction		5 0
Administration site swelling		3 0
Administration site urticaria		5 0
Administration site warmth		ı o
Puncture site bruise	50	
Puncture site haemorrhage		ı o
Puncture site pain	2.	ı o
Puncture site reaction		3 0
Puncture site swelling		ı o
Adverse effect absent		
No adverse event	22	2 0
Application and instillation site reactions		
Application site acne		ıl ol
Application site bruise	24	ا ا
Application site burn		3 0
Application site coldness		ıl ol
Application site discharge		ıl ol
Application site discolouration		ıl ol
Application site erythema	25	5 0
Application site exfoliation		ıl ol
Application site haemorrhage		ıl ol
Application site hypersensitivity		ı o
Application site inflammation		ı o
Application site joint pain		ıl ol
Application site pain	4.	ı o
Application site pruritus	18	
Application site rash		2 0
Application site scar		ı o
Application site swelling	4	ا ا
Application site vesicles	3	3 0
Application site warmth		ı o
Application site wound		ıl ol
Instillation site bruise		ıl ol
Instillation site discomfort		ıl ol
Instillation site pain		ا ا
Instillation site pruritus		ıl ol
Instillation site warmth	12	2 0
Asthenic conditions		
Asthenia	4086	3
Chronic fatigue syndrome	100	
Decreased activity		7 0
Fatigue	4346	
Malaise	10890	

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Reaction Name	Total	<u> Fatal</u>
General disorders General disorders cont'd		
Sluggishness	21	0
Body temperature altered		
Hyperthermia	g	
Hypothermia	48	3 0
Temperature regulation disorder	23	3 0
Complications associated with device NEC		
Complication of device removal	1	0
Injury associated with device	6	
Medical device site joint pain	1	0 ا
Phantom shocks	4	↓ 0
Death and sudden death		
Brain death	4	
Death	248	247
Drowning	1	0
Sudden death	27	7 27
Febrile disorders		
Hyperpyrexia	40	0
Masked fever	1	0
PFAPA syndrome	1	0 ا
Pyrexia	50949	0
Feelings and sensations NEC		
Chills	40438	3 0
Early satiety	1	0 ا
Feeling abnormal	2585	
Feeling cold	4813	3 0
Feeling drunk	113	
Feeling hot	2103	3 0
Feeling jittery	41	0
Feeling of body temperature change	874	l 0
Feeling of relaxation	1	0
Hangover	159	0
Hunger	69) o
Sensation of blood flow	10	0 (
Sensation of foreign body	39) o
Temperature intolerance	64	· 0
Thirst	1149	
Thirst decreased	g	
Fibrosis NEC		
Fibrosis	3	3 O
Gait disturbances		
Decreased gait velocity	3	3 O
Gait disturbance	311	0
Gait inability	160	
Loss of control of legs	40	1
General signs and symptoms NEC		
Apparent death	1	0
Chronic disease	1	ıl o
Condition aggravated	185	-
Crepitations	6	_
Crying	235	
Deformity	1	í ő
Developmental delay	4	
Discharge		8 0

	MedDRA Version: MedDRA 24.0		
Reaction Name	Tota	<u> Fat</u>	<u>al</u>
General disorders General disorders cont'd			
Disease progression		1	0
Disease recurrence		1	0
Effusion		1	0
Energy increased		21	0
Exercise tolerance decreased		26	0
Foaming at mouth		4	0
General physical health deterioration		18	1
General symptom		10	0
Glassy eyes		5	0
High-pitched crying		5	0
III-defined disorder		3	0
Illness	44	17	0
Induration		19	0
Influenza like illness	87		1
	07	2	,
Irritability postvaccinal Local reaction	11	54	0
	15		
Moaning		8	0
Multiple organ dysfunction syndrome		14	5
Nonspecific reaction		3	0
Organ failure		1	0
Perforation		1	0
Peripheral swelling	49		0
Pre-existing condition improved		[1]	0
Premature ageing		1	0
Prolapse		1	0
Screaming		21	0
Secretion discharge		25	0
Sensitivity to weather change		1	0
Stenosis		1	0
Swelling	228		0
Swelling face	8	56	0
Symptom recurrence		4	0
Tissue discolouration		1	0
Tissue infiltration		1	0
Unevaluable event		2	0
Healing abnormal NEC			
Impaired healing		2	0
Hemias NEC			
Hernia		2	0
Implant and catheter site reactions			
Catheter site urticaria		1	0
Implant site coldness		1	0
Implant site discharge		1	0
Implant site discolouration		3	0
Implant site hypoaesthesia		2	0
Implant site pain		4	0
Implant site rash		1	0
Implant site swelling		2	0
Implant site swelling		7	0
Inflammations		1	J
Granuloma		1	Λ
Inflammation	E-	78	0
			_
Systemic inflammatory response syndrome		3	0

Reaction Name General disorders General disorders cont'd Infusion site reactions Infusion site bruising Infusion site erythema	Total	<u>Fatal</u>
Infusion site reactions Infusion site bruising		
Infusion site bruising		
<u> </u>		
Infusion site ervthema		0
	2	0
Infusion site mass	2	0
Infusion site nodule	2	
Infusion site pain	11	0
Infusion site urticaria	1 1	0
Infusion site warmth	6	o
Injection site reactions		, and the second
Injected limb mobility decreased	32	0
Injection site atrophy	8	
Injection site bruising	103	
Injection site coldness	5	
Injection site cyst	3	
Injection site discolouration	4	
Injection site discomfort	16	-
Injection site discomment	10	o o
Injection site dryffess Injection site erythema	533	
Injection site erytherna Injection site exfoliation	1	0
Injection site extravasation	2	0
Injection site extravasation	2	
	13	
Injection site haemorrhage		
Injection site hypersensitivity	4	
Injection site hypoaesthesia		
Injection site indentation	12	
Injection site induration	[7	0
Injection site inflammation	57	
Injection site injury	4	0
Injection site irritation	3	
Injection site joint discomfort	1	0
Injection site joint erythema	8	
Injection site joint pain	34	
Injection site mass	1297	
Injection site movement impairment	3	0
Injection site muscle weakness	1 1	0
Injection site necrosis	4	0
Injection site nodule	4	0
Injection site oedema	25	
Injection site pain	4114	
Injection site papule	2	0
Injection site paraesthesia	22	
Injection site pruritus	268	
Injection site rash	279	
Injection site reaction	113	
Injection site scab	4	0
Injection site scar	5	
Injection site swelling	214	0
Injection site thrombosis		0
Injection site ulcer	1	0
Injection site urticaria	36	0
Injection site vesicles	11	
Injection site warmth	330	
Interactions		

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Reaction Name	Total	<u>Fatal</u>
General disorders General disorders cont'd		
Drug interaction	2	27 0
Inhibitory drug interaction		8 0
Mass conditions NEC		
Cyst		7 0
Mass	6	55 0
Nodule	1	5 0
Mucosal findings abnormal		
Mucosa vesicle		1 0
Mucosal disorder		1 0
Mucosal dryness		1 0
Mucosal haemorrhage		4 0
Mucosal inflammation		8 0
Mucosal pain		2 0
Mucosal ulceration		1 0
Oedema mucosal		3 0 2
Polyp		2 0
Necrosis NEC		
Fat necrosis		2 0
Necrosis		7 0
Oedema NEC		
Face oedema	3	sol o
Localised oedema	1	0 0
Oedema	5	6 0
Oedema peripheral	10	0 0
Pain and discomfort NEC		
Axillary pain	64	.7 O
Chest discomfort	171	9 0
Chest pain	416	67 0
Discomfort	44	.9 0
Facial discomfort	1	6 0
Facial pain	22	
Hernia pain		2 0
Inflammatory pain		8 0
Non-cardiac chest pain	3	34 0
Pain	1429	07 0
Suprapubic pain		1 0
Tenderness	171	8 0
Visceral pain		2 0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	12	28 1
Adverse event		7 0
Adverse reaction	4	3 0
Diet failure		1 0
Drug ineffective	12	21 0
Drug intolerance		4 0
Immediate post-injection reaction		4 0
Inadequate analgesia		21 0
No reaction on previous exposure to drug	5	60 o
Remission not achieved		1 0
Similar reaction on previous exposure to d	rug	1 0
Therapeutic product effect decreased		I
Therapeutic product effect incomplete		2 0
Therapeutic product ineffective		3 0

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name	Tota	<u>al </u>	Fatal
General disorders General disorders cont'd			
Therapeutic reaction time decreased		1	0
Therapeutic response decreased		1	0
Therapeutic response shortened		1	0
Therapeutic response unexpected		92	0
Therapy non-responder		3	0
Treatment failure		6	0
Vaccination failure		22	0
Vaccine positive rechallenge		1	0
Trophic disorders		- 1	J
Atrophy		3	0
Calcinosis		1	0
Dysplasia		2	0
Ulcers NEC			U
Ulcer		36	0
		2	0
Ulcer haemorrhage Vaccination site reactions		4	U
		17	0
Extensive swelling of vaccinated limb	ation	17	0
Shoulder injury related to vaccine administr	auon	34	0
Vaccination site atrophy		47	0
Vaccination site bruising		17	0
Vaccination site coldness		1	0
Vaccination site cyst		2	0
Vaccination site discharge		1	0
Vaccination site discolouration		10	0
Vaccination site discomfort		41	0
Vaccination site dryness		1	0
Vaccination site erythema	6	329	0
Vaccination site extravasation		1	0
Vaccination site granuloma		8	0
Vaccination site haemorrhage		6	0
Vaccination site hyperaesthesia		1	0
Vaccination site hypersensitivity		3	0
Vaccination site hypoaesthesia		23	0
Vaccination site induration		62	0
Vaccination site inflammation		46	0
Vaccination site injury		3	0
Vaccination site irritation		12	0
Vaccination site joint discomfort		_1	0
Vaccination site joint erythema		4	0
Vaccination site joint inflammation		_1	0
Vaccination site joint movement impairment		10	0
Vaccination site joint pain		41	0
Vaccination site joint swelling		3	0
Vaccination site joint warmth		1	0
Vaccination site lymphadenopathy		2	0
Vaccination site mass		77	0
Vaccination site movement impairment		61	0
Vaccination site nodule		1	0
Vaccination site oedema		3	0
Vaccination site pain		'99	0
Vaccination site papule		3	0
Vaccination site paraesthesia		12	0
Vaccination site pruritus	1	00	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site rash	162	0
Vaccination site reaction	20	0
Vaccination site scab	1	0
Vaccination site scar	4	0
Vaccination site swelling	447	0
Vaccination site urticaria	10	0
Vaccination site vesicles	9	0
Vaccination site warmth	346	0
Vascular complications associated with device		
Vascular stent occlusion	1	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	7	0
Withdrawal syndrome	77	0
General disorders SOC TOTAL	222324	291

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Hepatic disorders		
Bile duct infections and inflammations		
Biliary colic	25	0
Cholangitis	3	0
Cholecystitis and cholelithiasis		
Cholecystitis	11	0
Cholelithiasis	10	0
Cholestasis and jaundice		
Cholestasis	5	0
Jaundice	41	0
Jaundice cholestatic	7	0
Ocular icterus	1	0
Gallbladder disorders NEC		
Gallbladder disorder	1	0
Gallbladder oedema	1	0
Hepatic and hepatobiliary disorders NEC		
Liver disorder	10	0
Hepatic enzymes and function abnormalities		
Hepatic function abnormal	7	0
Hepatic failure and associated disorders		
Acute hepatic failure	1	0
Hepatic failure	4	0
Subacute hepatic failure	1	0
Hepatic fibrosis and cirrhosis		
Hepatic cirrhosis	6	0
Hepatic vascular disorders		
Budd-Chiari syndrome	1	1
Hepatic artery thrombosis	1	0
Hepatic haemorrhage	1	0
Hepatic infarction	2	1
Hepatic vascular thrombosis	2	0
Hepatic vein thrombosis	11	0
Portal hypertension	1	0
Portal vein phlebitis	1	0
Portal vein thrombosis	51	4
Portosplenomesenteric venous thrombosis	2	0
Hepatobiliary signs and symptoms	_	Ŭ
Hepatic pain	52	0
Hepatomegaly	3	0
Liver tenderness	4	0
Hepatocellular damage and hepatitis NEC	i i	J
Autoimmune hepatitis	2	0
Drug-induced liver injury	1	0
Hepatic necrosis	1	0
Hepatic steatosis	5	0
Hepatitis	20	0
Hepatitis acute	6	1
Immune-mediated hepatitis	1	0
Ischaemic hepatitis	1	0
Liver injury	17	0
Reye's syndrome	1	0
Obstructive bile duct disorders (excl neoplasms)		U
Sphincter of Oddi dysfunction	2	0
Hepatic disorders SOC TOTAL	323	
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Name: COVID-19 AstraZeneca Vaccine Analysis Print
Report Run Date: 28-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 26-May-2021 19:00:03
MedDRA Version: MedDRA 24.0

	RA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Immune system disorders		
Acute and chronic sarcoidosis		
Sarcoidosis	2	I 0
Allergic conditions NEC		
Allergic oedema	19	
Allergy to animal		ıl ol
Allergy to arthropod sting		<u>2</u> 0
Allergy to metals		ıl ol
Allergy to sting		ıl ol
Allergy to venom		ıl ol
Dust allergy		ıl ol
Hypersensitivity	117	ا ا
Infusion related hypersensitivity reaction	Į.	-l -l
Mite allergy		
Multiple allergies	13	
Serum sickness	15	
Serum sickness-like reaction	13	
Type I hypersensitivity		
Type III immune complex mediated reaction	Į.	5 0
Type IV hypersensitivity reaction		
Allergies to foods, food additives, drugs and other		
Allergic reaction to excipient	,	ıl ol
Allergy to chemicals		
Allergy to vaccine	44	
Contrast media reaction		
Drug hypersensitivity	58	
Food allergy	18	
Oral allergy syndrome		íl ő
Reaction to colouring		
Reaction to excipient	13	3 0
Reaction to preservatives	14	
Rubber sensitivity		il ol
Smoke sensitivity		_
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	576	3 2
Anaphylactic shock	102	
Anaphylactoid reaction	20	
Anaphylactoid shock		
Atopic disorders		
Atopy	2	2 0
Seasonal allergy	69	
Autoimmune disorders NEC		
Autoimmune disorder	28	3 0
Endocrine autoimmune disorders		1
Hashitoxicosis		1 0
Immune and associated conditions NEC]
Bacille Calmette-Guerin scar reactivation	27	7 0
Cytokine release syndrome		ا ا
Cytokine storm		0
Haemophagocytic lymphohistiocytosis		
Immune system disorder	17	
Immune-mediated adverse reaction	' <u>'</u>	7 0
Immunisation reaction		ا ا
Pre-engraftment immune reaction		il ő

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 28-May-2021
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Reaction Name	Total	Fatal
Immune system disorders ne system disorders cont'd		
Sensitisation	28	0
Immunodeficiency disorders NEC		
Immunodeficiency	3	0
Immunosuppression	5	0
Transplant rejections		
Corneal graft rejection	2	0
Transplant rejection	6	0
Vasculitides		
Eosinophilic granulomatosis with polyangiitis	1	0
Immune system disorders SOC TOTAL	2347	2

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Infections			
Abdominal and gastrointestinal infections			
Abdominal infection		1	0
Abdominal wall infection		1	0
Anal abscess		1	0
Appendicitis		26	0
Appendicitis perforated		3	0
Diarrhoea infectious		3	0
Diverticulitis		20	0
Dysentery		4	0
Gastroenteritis		30	0
Gastrointestinal infection		5	0
Large intestine infection		2	0
Peritonitis		2	0
Bacterial infections NEC			
Administration site cellulitis		1	0
Arthritis bacterial		4	0
Bacterial infection		24	1
Bacterial vaginosis		2	0
Cellulitis		451	1
Ear infection bacterial		1	0
Endocarditis bacterial		2	0
Eye infection bacterial		2	0
Folliculitis		9	0
Injection site cellulitis		7	0
Perichondritis		1	0
Periorbital cellulitis		2	0
Pneumonia bacterial		4	1
Post procedural cellulitis		1	0
Skin bacterial infection		4	0
Urinary tract infection bacterial		4	0
Vaccination site cellulitis		20	0
Bone and joint infections			
Abscess jaw		1	0
Arthritis infective		2	0
Intervertebral discitis		2	0
Osteomyelitis		1	0
Bordetella infections			
Pertussis		3	0
Borrelial infections			
Erythema migrans		2	0
Lyme disease		2 7	0
Relapsing fever		1	0
Breast infections			
Mastitis		25	0
Brucella infections			
Brucellosis		1	0
Caliciviral infections			
Gastroenteritis norovirus		1	0
Campylobacter infections			
Campylobacter colitis		1	0
Candida infections			
Anal candidiasis		1	0
Balanitis candida		1	0

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MedDRA Version: MedDRA 24.0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.		
Reaction Name	Total_	<u>Fatal</u>
Infections Infections cont'd		
Candida infection	48	0
Oral candidiasis	38	0
Skin candida	2	0
Vulvovaginal candidiasis	39	0
Cardiac infections		
Endocarditis	2	0
Central nervous system and spinal infections		
Cavernous sinus thrombosis	5	0
Central nervous system infection	1	0
Encephalitis	28	0
Encephalomyelitis	2	0
Extradural abscess	1	0
Meningitis	22	0
Myelitis	11	0
Chlamydial infections		
Chlamydial infection	1	0
Clostridia infections		
Clostridium difficile colitis	2 2	0
Clostridium difficile infection		0
Tetanus	2	0
Coronavirus infections		
Asymptomatic COVID-19	3	0
COVID-19	401	22
COVID-19 pneumonia	23	7
Coronavirus infection	4	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	5	0
Suspected COVID-19	34	0
Corynebacteria infections		
Diphtheria	2	0
Coxiella infections		
Q fever	105	0
Dental and oral soft tissue infections		
Abscess oral	3	0
Gingival abscess	5	0
Gingivitis	22	0
Lip infection	1	0
Oral infection	1	0
Oral pustule	2	0
Parotitis	10	0
Pericoronitis	2	0
Periodontitis	1	0
Sialoadenitis	2 3 13	0
Tongue abscess	3	0
Tooth abscess		
Tooth infection	11	0
Ear infections		
Ear infection	80	
Labyrinthitis	122	0
Mastoiditis	3	
Otitis externa	3	0
Otitis media	12	0
Otosalpingitis	1	0

	MedDRA Version: MedDRA 24.0		
Reaction Name	_	<u>Total</u>	<u>Fatal</u>
Infections Infections cont'd			
Ectoparasitic infestations			
Acarodermatitis		2	0
Infestation		1	0
Trombidiasis		2	0
Epstein-Barr viral infections			
Epstein-Barr virus infection		2	0
Infectious mononucleosis		43	0
Escherichia infections			
Escherichia infection		2	0
Escherichia sepsis		2	0
Eye and eyelid infections			
Conjunctivitis		65	0
Eye infection		21	0
Eyelid boil		3	0
Eyelid infection		3	0
Hordeolum		27	0
Keratouveitis		1	0
Retinitis		2	0
Female reproductive tract infections			U
Endometritis		1	0
			_
Pelvic inflammatory disease			0
Pyometra Vaginal shapes			1
Vaginal infection		1	0
Vaginal infection		4	0
Flaviviral infections		ا	^
Yellow fever		1	0
Yellow fever vaccine-associated neurotropic	c disease	1	0
Fungal infections NEC		ار	_
Ear infection fungal		1	0
Fungal infection		14	0
Fungal skin infection		5	0
Oral fungal infection		1	0
Severe asthma with fungal sensitisation		4	0
Tonsillitis fungal		1	0
Vulvovaginal mycotic infection		3	0
Hepatitis virus infections			•
Hepatitis E		1	0
Hepatobiliary and spleen infections		_	
Biliary sepsis		5	1
Herpes viral infections			•
Eczema herpeticum		3	0
Genital herpes		48	0
Genital herpes simplex		1	0
Haemorrhagic varicella syndrome		1	0
Herpes dermatitis		2	0
Herpes ophthalmic		14	0
Herpes simplex		33	0
Herpes simplex reactivation		2	0
Herpes virus infection		12	0
Herpes zoster		1061	0
Herpes zoster oticus		10	0
Herpes zoster reactivation		2	0
Meningoencephalitis herpetic		1	0

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	dDRA Version: MedDRA 24.0		
Reaction Name	Tota	<u> Fat</u>	<u>:al</u>
Infections Infections cont'd			
Nasal herpes		14	0
Ophthalmic herpes simplex		1	0
Ophthalmic herpes zoster		7	0
Oral herpes	60	00	0
Varicella		30	0
Varicella zoster virus infection		1	0
Infections NEC			
Abscess		28	0
Abscess limb		16	0
Abscess soft tissue		2	0
Catheter site infection		1	0
Coinfection		1	0
Device related infection		1	0
Genital abscess		1	0
Groin infection		1	0
Infected bite		2	0
Infected cyst		2	0
Infection	39	92	3
Infection in an immunocompromised host		3	3 0
Infectious thyroiditis		1	0
Injection site abscess		3	0
Injection site infection		15	0
Localised infection		93	0
Lymph gland infection		3	0
Omphalitis		1	0
Pathogen resistance		2	0
Respiratory tract infection		2	0
Toxic shock syndrome		1	0
Vaccination site abscess		3	0
Vaccination site infection		22	0
Vestibulitis		3	0
Wound abscess		1	0
Infectious disorders carrier			
SARS-CoV-2 carrier		1	0
Infectious transmissions			
Secondary transmission		9	0
Vaccine virus shedding		1	0
Influenza viral infections			
H2N2 influenza		2	0
Influenza	61	16	0
Klebsiella infections			
Pneumonia klebsiella		1	0
Lower respiratory tract and lung infections			
Atypical pneumonia		2	0
Bronchitis		19	0
Infectious pleural effusion		4	0
Infective exacerbation of bronchiectasis		1	0
Lower respiratory tract infection	2 ⁻	11	3
Pleural infection		1	0
Pneumonia	1	77	17
Sputum purulent		1	0
Male reproductive tract infections			
Epididymitis		5	0

Earliest Reaction Date: 03-Feb-1921 MedDRA V	ersion: MedDRA 24.0	Fatal
Infections Infections cont'd	<u> </u>	ı alaı
Orchitis	1	0
Mumps viral infections		
Mumps	6	6 0
Muscle and soft tissue infections		,
Muscle abscess	1	0
Soft tissue infection	5	
		,
Orthopox viral infections Cow pox		0
Paravaccinia infections		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Paravaccinia imecuoris Paravaccinia		0
Plasmodia infections		1
Malaria	6	0
Pneumocystis infections		1
Pneumocystis jirovecii pneumonia		0
Polyomavirus infections		1
Progressive multifocal leukoencephalopathy		0
Prion-associated disorders		
Creutzfeldt-Jakob disease	3	0
Retroviral infections		1
Acquired immunodeficiency syndrome	2	2 0
HIV-associated neurocognitive disorder	2	
Rubella viral infections		
Rubella	1	0
Rubeola viral infections		
Measles	4	l o
Salmonella infections		ĺ
Typhoid fever	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Abdominal sepsis	1	0
Bacteraemia	1	il o
Neutropenic sepsis	3	
Sepsis	75	1
Sepsis syndrome	1	0
Septic pulmonary embolism	1	0
Septic rash	Ş	
Septic shock	5	2
Urosepsis	5	
Viraemia	3	
Skin structures and soft tissue infections		
Carbuncle	1	0
Dermatitis infected	10	0
Eczema infected	1	0
Impetigo	6	0
Infected dermal cyst	3	0
Pilonidal cyst	2	0
Pustule	14	· 0
Rash pustular	17	7 0
Skin infection	60	0
Subcutaneous abscess		0
Vaccination site pustule	4	o ا
Staphylococcal infections		
Furuncle	39	0
Staphylococcal bacteraemia	2	

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	Fatal
Infections Infections cont'd			
Staphylococcal scalded skin syndrome		1	0
Staphylococcal sepsis		3	1
Toxic shock syndrome staphylococcal		2	0
Vulvovaginitis staphylococcal		1	0
Streptococcal infections			
Cellulitis streptococcal		1	0
Erysipelas		1	0
Pharyngitis streptococcal		7	0
Scarlet fever		1	0
Streptococcal infection		1	0
Tonsillitis streptococcal		1	0
Tinea infections			
Body tinea		3	0
Tinea cruris		1	0
Tinea infection		1	0
Tinea pedis		2	0
Tinea versicolour		1	0
Treponema infections			
Syphilis		3	0
Trypanosomal infections			
African trypanosomiasis		6	0
Tuberculous infections			
Disseminated Bacillus Calmette-Guerin inf	ection	1	0
Lymph node tuberculosis		3	0
Meningitis tuberculous		1	0
Pulmonary tuberculosis		2	0
Tuberculosis		4	0
Upper respiratory tract infections			
Acute sinusitis		4	0
Chronic sinusitis		13	0
Croup infectious		1	0
Epiglottitis		1	0
Laryngitis		21	0
Nasal vestibulitis		1	0
Nasopharyngitis		1535	0
Pharyngitis		26	0
Rhinitis		41	0
Sinobronchitis		1	0
Sinusitis		286	0
Tonsillitis		63	0
Tracheitis		1	0
Upper respiratory tract infection		6	0
Urinary tract infections			
Cystitis		72	0
Genitourinary tract infection		1	0
Kidney infection		41	0
Pyelonephritis		4	0
Pyelonephritis chronic		1	0
Urinary tract infection		174	0
Vascular infections			
Haematoma infection		2	0
Infected lymphocele		1	0
Infected varicose vein		1	0

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Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 28-May-2021
Earliest Reaction Date: 03-Feb-1921

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MedDRA Version: MedDRA 24.0

Reaction Name	<u>Total</u>	Fatal
Infections Infections	cont'd	
Lymphangitis		6 0
Viral infections NEC		
Arthritis viral		1 0
Bronchitis viral		1 0
Ear infection viral		1 0
Encephalitis viral		7 0
Eye infection viral		1 0
Gastritis viral		1 0
Gastroenteritis viral	6	2 0
Gastrointestinal viral infect	tion	1 0
Hepatitis viral		2 0
Meningitis viral	10	6 0
Pneumonia viral		6 1
Post viral fatigue syndrome		
Sweating fever	69	
Vestibular neuronitis	23	2 0
Viral diarrhoea		4 0
Viral infection	5	8 0
Viral labyrinthitis		6 0
Viral myocarditis		2 0
Viral pericarditis		1 0
Viral pharyngitis	2	
Viral rash	6	
Viral sepsis		1 0
Viral sinusitis		1 0
Viral tonsillitis		1 0
Infections SOC TOTAL	1472	6l 70

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Injuries		
Abdominal and gastrointestinal injuries NEC		
Abdomen crushing	3	0
Colon injury	1	0
Lip injury	2	0
Mouth injury	1	0
Oral contusion	11	0
Palate injury	1	0
Splenic rupture	3	0
Tongue injury	2	ő
Tooth fracture	1	0
Tooth injury	1	0
Accidental exposures to product		J
Accidental exposures to product Accidental exposure to product	15	0
Anaesthetic and allied procedural complications	13	U
Anaesthetic complication	2	0
Anaesthetic complication neurological	3	0
Delayed recovery from anaesthesia	1	
Sedation complication	2	0
·		0
Atmospheric pressure injuries	4	0
Barotrauma	1	0
Decompression sickness	1	0
Hypobarism	2	0
Bone and joint injuries NEC	0	0
Bursa injury	2	0
Cartilage injury	7	0
Joint injury	/	0
Synovial rupture	2	0
Cardiac and vascular procedural complications	4	
Ischaemic contracture of the left ventricle	1	0
Vascular access site bruising	1	0
Vascular graft thrombosis	1	0
Vasoplegia syndrome	1	0
Cardiovascular injuries		
Heart injury	4	0
Vascular injury	4	0
Cerebral injuries NEC		
Brain contusion	10	0
Brain herniation	4	0
Concussion	5	0
Craniocerebral injury	1	0
Epidural haemorrhage	1	0
Extradural haematoma	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	1
Subdural haemorrhage	3	0
Chemical injuries		
Chemical burn	1	0
Chemical burn of oral cavity	1	0
Chemical burn of skin	4	0
Chemical phlebitis	2	0
Chest and respiratory tract injuries NEC		
Chest crushing	11	0
Chest injury	1	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Injuries cont'd		
Foreign body in throat	1	0
Traumatic lung injury	1	0
Conditions caused by cold		
Chillblains	58	0
Frostbite	1	0
Cranial nerve injuries		
Cranial nerve injury	1	0
Optic nerve injury	2	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	7	0
Exposure via breast milk	42	
Foetal exposure during pregnancy	40	0
Maternal exposure during breast feeding	1004	
Maternal exposure during pregnancy	216	
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	4	0
Paternal exposure during pregnancy	17	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to toxic agent	1	o
Exposure to vaccinated person	1	0
Eye injuries NEC		
Cataract traumatic	1	0
Eye contusion	45	-
Eye injury	23	
Eyelid contusion	3	
Foreign body in eye	1	o o
Hyphaema	1	Ö
Injury corneal	1	o o
Periorbital haematoma	1	Ö
Periorbital haemorrhage	1	o o
Retinal injury	3	
Superficial injury of eye	1	Ö
Fractures and dislocations NEC	i i	
Fracture	1	0
Joint dislocation	8	ő
Multiple fractures	1	Ö
Stress fracture	4	Ö
Gastrointestinal and hepatobiliary procedural complications	· ·	Ĭ
Peripancreatic fluid collection	1	0
Procedural nausea	24	
Procedural vomiting	7	Ö
Heat injuries (excl thermal burns)	'	Ĭ
Heat exhaustion	4	0
Heat illness	1	o o
Heat oedema	13	
Heat stroke	7	0
1.55.55	1	0
Intentional product misuses	3	0
Intentional product misuse	3	l
Intentional product use issues	1	
Intentional product use issue	1	0
Limb fractures and dislocations	_	_
Ankle fracture	3	I 0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	_Total_	<u>Fatal</u>
Injuries Injuries cont'd		
Atypical femur fracture	1	0
Clavicle fracture	15	0
Femoral neck fracture	2 2	0
Femur fracture		0
Foot fracture	1	0
Humerus fracture	1	0
Lower limb fracture	2	0
Patella fracture	1	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	5	0
Device use issue	1	0
Dose calculation error	1	0
Drug titration error	1	0
Inadequate aseptic technique in use of product	2 2	0
Intercepted medication error		0
Medication error	37	0
Product use issue	3	0
Vaccination error	7	0
Wrong device used	1	0
Wrong drug	4	0
Wrong schedule	1	0
Wrong technique in product usage process	6	0
Muscle, tendon and ligament injuries		
Epicondylitis	12	0
Ligament injury	3	0
Ligament rupture	1	0
Ligament sprain	16	0
Muscle injury	30	0
Muscle rupture	13	0
Muscle strain	37	0
Post-traumatic neck syndrome	3	0
Repetitive strain injury	2	0
Tendon injury	3	0
Tendon rupture	12	0
Nerve injuries NEC		
Nerve injury	81	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	8	0
Procedural dizziness	29	0
Non-occupational environmental exposures		
Exposure to chemical pollution	1	0
Exposure to extreme temperature	4	0
Exposure to noise	2	0
Non-site specific injuries NEC		
Animal bite	1	0
Arthropod bite	4	0
Arthropod sting	10	0
Bite	1	0
Electric shock	23	0
Fall	200	1

COVID-19 AstraZanaca Vaccina Analysis

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Injuries cont'd			
Inflammation of wound		3	0
Injury		11	0
Internal injury		1	0
Nervous system injury		2	0
Post concussion syndrome		2	0
Road traffic accident		2 1	0
Soft tissue injury		1	0
Tissue injury		1	0
Traumatic haematoma		3	0
Traumatic shock		1	0
Wound		6	0
Wound complication		12	0
Wound haemorrhage		8	0
Wound secretion		2	0
Non-site specific procedural complications			
Incision site erythema		1	0
Incision site haemorrhage		1	0
Incision site oedema		1	0
Incision site pain		9	0
Infusion related reaction		19	0
Injection related reaction		584	0
Needle fatigue		1	0
Post procedural complication		35	0
Post procedural contusion		2	0
Post procedural haematoma		1	0
Procedural hypertension		1	0
Procedural pain		7	0
Procedural site reaction		1	0
Suture related complication		1	0
Occupational exposures			
Occupational exposure to product		1	0
Off label uses			
Off label use		11	0
Overdoses NEC			
Intentional overdose		4	0
Overdose		19	0
Pathways and sources of exposure			
Exposure via body fluid		1	0
Exposure via unknown route		1	0
Peripheral nerve injuries			
Brachial plexus injury		2	0
Median nerve injury		2 1	0
Sciatic nerve injury		1	0
Ulnar nerve injury		1	0
Poisoning and toxicity			
Alcohol poisoning		3	0
Chemical poisoning		1	0
Metal poisoning		1	0
Poisoning		5	0
Systemic toxicity		1	0
Toxicity to various agents		8	0
Product administration errors and issues			
Accidental overdose		3	0

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 28-May-2021

Data Lock Date: 26-May-2021 19:00:03

Farliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Injuries cont'd		
Accidental underdose	2	0
Contraindicated product administered	4	0
Duplicate therapy error	2	0
Expired product administered	24	0
Extra dose administered	5	0
Inappropriate schedule of product administration	12	0
Incomplete course of vaccination	2	0
Incorrect dose administered	4	0
Incorrect product administration duration	1	0
Incorrect product formulation administered	1	0
Incorrect route of product administration	20	0
Intercepted product administration error	2	0
Lack of vaccination site rotation	1	0
Product administered at inappropriate site	11	0
Product administered to patient of inappropriate age	14	0
Product administration error	15	0
Product dose omission issue	3	0
Wrong patient received product	1	0
Wrong product administered	14	0
Product confusion errors and issues		_
Product label confusion	1	0
Product name confusion	1	0
Product dispensing errors and issues		
Product dispensing error	12	0
Product monitoring errors and issues		
Documented hypersensitivity to administered product	1	0
Product monitoring error	1	0
Product prescribing errors and issues		
Contraindicated product prescribed	7	0
Product prescribing error	2	0
Product selection errors and issues		
Product selection error	1	0
Product storage errors and issues in the product use system		
Intercepted product storage error	1	0
Product storage error	2	0
Radiation injuries		
Sunburn	37	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Kidney rupture	1	0
Reproductive system and breast injuries		
Penile contusion	2	0
Reproductive tract and breast procedural complications		
Postmastectomy lymphoedema syndrome	1	0
Respiratory tract and thoracic cavity procedural complications		
Pulmonary oil microembolism	1	0
Site specific injuries NEC		
Back injury	7	0
Central nervous system injury	1	0
Face crushing	1	0
Face injury	2	0
Head injury	31	0
Limb crushing injury	7	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: Med		
Reaction Name	Total	<u>Fatal</u>
Injuries Injuries cont'd		
Limb injury	192	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	3	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	2383	0
Nail injury	1	0
Scar	19	0
Scratch	3	0
Skin abrasion	5	0
Skin injury	11	0
Skin laceration	1	0
Skin pressure mark	1	0
Skin wound	6	0
Subcutaneous haematoma	1	0
Skin procedural complications		
Recall phenomenon	1	0
Spinal cord injuries NEC		
Prevertebral soft tissue swelling of cervical space	1	l 0
Spinal cord injury	1	0
Spinal cord injury sacral	1	l 0
Spinal fractures and dislocations		
Spinal compression fracture	3	l 0
Spinal fracture	4	
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma obstruction	1	0
Stoma site haemorrhage	1	0
Stoma site pain	1	0
Stoma site rash	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	4	0
Burn oral cavity	8 7	0
Burns second degree	7	0
Cold burn	3	
Thermal burn	46	0
Thermal burns of eye	39	0
Transplantation complications		
Transplant failure	1	0
Underdoses NEC		
Intentional underdose	1	0
Underdose	2	0
Vaccination related complications		
Adverse event following immunisation	4	0
Post vaccination syndrome	1	0
Reaction to previous exposure to any vaccine	1	0
Vaccination complication	90	0
Injuries SOC TOTAL	6189	0 2

	Total	
	<u>rolar</u>	Fatal
Investigations		
Adrenal cortex tests		
Blood cortisol	1	0
Cortisol decreased	1	0
Cortisol increased	1	0
Adrenal medulla tests		
Epinephrine increased	1	0
Norepinephrine increased	2	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	6	0
Audiogram	1	0
Autoimmunity analyses		
Antimitochondrial antibody positive	1	0
Antinuclear antibody positive	1	0
Antiphospholipid antibodies	1	0
Antiphospholipid antibodies positive	1	0
Cold agglutinins positive	1	0
DNA antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	2	0
Bacteria identification and serology (excl mycobacteria)		
Bacterial test	1	0
Staphylococcus test positive	1	0
Blood counts NEC		
Blood count	8	0
Blood count abnormal	3	0
Full blood count	6	0
Full blood count abnormal		0
Full blood count decreased	2 2	0
Full blood count increased	1	0
Blood gas and acid base analyses		
Blood gases	1	0
Blood lactic acid	2	0
Blood lactic acid increased	4	0
Blood pH	13	0
Blood pH increased	11	0
Carbon dioxide increased	1	0
Oxygen consumption	1	0
Oxygen saturation	23	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	162	1
Blood grouping and cross-matching analyses		
Blood group O	2	0
Rhesus antigen negative	1	0
Bone marrow and immune tissue imaging procedures		
Scan lymph nodes	2	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	19	0
Blood glucose abnormal	15	0
Blood glucose decreased	35	0
Blood glucose fluctuation	28	Ö
Blood glucose increased	165	Ö
Glycosylated haemoglobin increased	2	0
Cardiac auscultatory investigations	_	- J

COVID-19 AstraZeneca Vaccine Analysis

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 28-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 26-May-2021 19:00:03
MedDRA Version: MedDRA 24.0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total </u>	<u>Fatal</u>
Investigations Investigations cont'd		
Cardiac murmur	21	0
Heart sounds	14	0
Heart sounds abnormal	6	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	2	0
Myocardial strain	14	0
Stroke volume decreased	1	0
Venous pressure jugular increased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
Prostatic specific antigen	1	0
Prostatic specific antigen increased	2	0
Central nervous system histopathology procedures		
Biopsy brain	1	0
Central nervous system imaging procedures		_
Computerised tomogram head	15	0
Magnetic resonance imaging head	38	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	4	0
Chemistry analyses NEC		
Histamine abnormal	2	0
Histamine level	1	0
Histamine level increased	1	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	4	0
Cholesterol analyses		
Blood cholesterol increased	6	0
Low density lipoprotein	1	0
Low density lipoprotein increased	1	0
Very low density lipoprotein decreased	1	0
Coagulation and bleeding analyses	[
Activated partial thromboplastin time	1	0
Activated partial thromboplastin time prolonged	98	0
Bleeding time	4	0
Bleeding time abnormal	3	0
Bleeding time prolonged	3	
Blood fibrinogen decreased	7	0
Blood fibrinogen increased	2	0
Blood thromboplastin	1	0
Blood thromboplastin abnormal	2	0
Coagulation factor	1	0
Coagulation factor VIII level decreased	1	0
Coagulation time	6	0
Coagulation time prolonged	11	0
Coagulation time prolonged Coagulation time shortened	2	0
Fibrin D dimer	3	0
Fibrin D dimer Fibrin D dimer decreased		_
	35	0
Fibrin D dimer increased	35	U

	ledDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Investigations Investigations cont'd			
International normalised ratio		2	0
International normalised ratio abnormal		10	0
International normalised ratio decreased		38	0
International normalised ratio fluctuation		3	0
International normalised ratio increased		79	0
Prothrombin level increased		1	0
Prothrombin time prolonged		1	0
Thrombin time		1	0
Digestive enzymes		·	•
Amylase increased		1	0
Pancreatic enzymes increased		1	0
ECG investigations			·
Cardiac telemetry		1	0
Electrocardiogram		3	0
Electrocardiogram QT prolonged		1	0
Electrocardiogram ST segment elevation			0
Electrocardiogram ST-T segment abnormal		2 7	0
Electrocardiogram T wave inversion		3	0
Electrocardiogram abnormal		12	0
Electrocardiogram change		1	0
Electrocardiogram normal			
l — — — — — — — — — — — — — — — — — — —		1	0
Exercise electrocardiogram		1	U
Endocrine analyses and imaging NEC		17	0
Hormone level abnormal		17	0
Faecal analyses NEC		7	0
Faecal calprotectin increased			0
Stool analysis abnormal		1	0
Fertility analyses		٦	_
Semen volume decreased		2	0
Foetal and neonatal diagnostic procedures		4	0
Foetal heart rate	di	1	0
Gastrointestinal and abdominal imaging proced	dures	4	0
Computerised tomogram abdomen		4	0
Gastrointestinal function diagnostic procedures	5	ا	_
Gastric pH		1	0
Gastric pH decreased		2	0
Gastrointestinal stoma output increased		1	0
Swallow study		3	0
Gastrointestinal, pancreatic and APUD hormon	ne analyses		0
Blood gastrin		1	0
Blood gastrin normal		1	0
Blood insulin		4	0
Blood insulin decreased		2	0
Blood insulin increased		3	0
Haematological analyses NEC			•
Blood viscosity abnormal		1	0
Blood viscosity decreased		1	0
Blood viscosity increased		1	0
Haematology test abnormal		1	0
Plasma viscosity abnormal		1	0
Red blood cell sedimentation rate increased		5	0
Heart rate and pulse investigations			_
Brachial pulse decreased		1	0

COVID-19 AstraZeneca Vaccine Analysis

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA Ver		
Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate	937	0
Heart rate abnormal	46	0
Heart rate decreased	99	0
Heart rate increased	1807	0
Heart rate irregular	146	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	6	0
Maximum heart rate decreased	1	0
Orthostatic heart rate response increased	1	0
Pulse abnormal	20	0
Pulse absent	4	0
Pulse pressure abnormal	1	0
Pulse pressure increased	3	0
Pulse waveform abnormal	1	0
Sinus rhythm	5	0
Imaging procedures NEC		
Computerised tomogram	7	0
Magnetic resonance imaging	1	0
Scan	1	0
X-ray	1	0
Immune response protein analyses NEC		
C1 esterase inhibitor test	1	0
Immunoglobulin analyses		
Blood immunoglobulin E	1	0
Blood immunoglobulin E increased	2	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunology analyses NEC		
Antibody test	1	0
Antibody test abnormal	1	0
Antibody test negative	3	0
Immunology test	6	0
Immunology test normal	1	0
Mast cell degranulation present	1	0
Immunology skin tests NEC		
Allergy alert test	2	0
Skin test positive	4	0
Investigations NEC		
APACHE II score	1	0
Blood test	38	0
Blood test abnormal	41	0
Laboratory test	1	0
Polymerase chain reaction positive	2	0
Liver function analyses		
Alanine aminotransferase increased	16	0
Aspartate aminotransferase increased	3	0
Bile output	3	0
Blood bilirubin	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme abnormal	1	0
Hepatic enzyme increased	10	0

Name: COVID-19 AstraZeneca Vaccine Analysis Print
Report Run Date: 28-May-2021
Earliest Reaction Date: 03-Feb-1921

Data Lock Date: 26-May-2021 19:00:03
MedDRA Version: MedDRA 24.0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Investigations Investigations cont'd		
Liver function test	3	3 0
Liver function test abnormal	26	3 0
Liver function test increased	5	5 0
Transaminases increased	8	3 0
Metabolism tests NEC		
Blood ketone body		el ol
Ubiquinone	3	3 0
Ubiquinone decreased	2	
Urine ketone body present	1	ıl ol
Microbiology and serology tests NEC		
Blood culture	2	2 0
Blood culture negative	1	0
Septic screen	1	ıl ol
Mineral and electrolyte analyses		
Blood calcium	1	ıl ol
Blood calcium increased	1	0
Blood iron	g	
Blood iron decreased	7	⁷ 0
Blood iron increased	1	ıl ol
Blood magnesium decreased	2	2 0
Blood phosphorus abnormal	1	ıl ol
Blood phosphorus decreased	Ę	5 0
Blood phosphorus increased	2	
Blood potassium decreased	6	
Blood potassium increased	7	1 1
Blood sodium	2	
Blood sodium decreased	4	1 1
Serum ferritin	1	0
Serum ferritin decreased	2	2 0
Serum ferritin increased	1	0
Sweat test	1	ıl ol
Urine copper	1	1 0
Musculoskeletal and soft tissue imaging prod	redures	
Bone densitometry	1	1 0
Skull X-ray	6	3 0
X-ray of pelvis and hip	1	0 ا
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	2	2 0
Swollen joint count increased		2 0
Tender joint count	3	3 0
Mycobacteria identification and serology		
Interferon gamma release assay positive	1	0 0
Neurologic diagnostic procedures		
Coma scale abnormal	15	5 0
Electromyogram abnormal	1	ı o
Joint position sense decreased	1	0 0
Lumbar puncture	12	2 0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	2	
Intraocular pressure increased	2	2 0
Intraocular pressure test	6	0
Visual tracking test	1	1
Physical examination procedures and organ	system status	

Case Series Drug Analysis Print COVID-19 AstraZeneca Vaccine Analysis P

	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Investigations Investigations cont'd			
Body height decreased		1	0
Body surface area		2	0
Body temperature		958	0
Body temperature abnormal		75	0
Body temperature decreased		125	0
Body temperature fluctuation		163	0
Body temperature increased		1050	0
Body temperature normal		2	0
Breath sounds		1	0
Breath sounds abnormal		5	0
Dermatologic examination abnormal		1	0
General physical condition abnormal		2	0
Grip strength		2 6	0
Grip strength decreased		29	0
Head lag		17	0
Lymph node palpable		5	0
Male genital examination abnormal		1	0
Menstruation normal		1	0
Muscle strength abnormal		3	0
Neurological examination		1	0
Neurological examination normal		1	0
Palpatory finding abnormal		1	0
Psoriasis area severity index decreased		1	0
Respiratory rate		10	0
Respiratory rate decreased		23	0
Respiratory rate increased		71	0
Skin temperature		167	0
Temperature difference of extremities		5	0
Urological examination		1	0
Vital signs measurement		1	0
Weight decreased		133	0
Weight increased		27	0
Pituitary analyses anterior			
Blood corticotrophin		1	0
Blood prolactin increased		1	0
Blood thyroid stimulating hormone		1	0
Blood thyroid stimulating hormone decrease	ed	2	0
Blood thyroid stimulating hormone increase	d	4	0
Platelet analyses			
Platelet count		2	0
Platelet count abnormal		1	0
Platelet count decreased		217	0
Platelet count increased		5	0
Platelet count normal		1	0
Protein analyses NEC			
C-reactive protein abnormal		2	0
C-reactive protein increased		16	0
Protein total increased		1	0
Red blood cell analyses		·	
Haematocrit		8	0
Haematocrit decreased		1	0
Haematocrit increased		1	0
Haemoglobin		4	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name	<u>_</u> _	<u>Total</u>	Fatal
Investigations Investigations cont'd			
Haemoglobin decreased		10	0
Mean cell haemoglobin concentration		1	0
Mean cell volume abnormal		2	0
Red blood cell count		1	0
Red blood cell count decreased		2	0
Renal function analyses			
Blood creatine increased		1	0
Blood creatinine abnormal		1	0
Blood creatinine decreased		2	0
Blood creatinine increased		2	0
Blood urea		5	0
Blood urea increased		1	0
Glomerular filtration rate decreased		1	0
Reproductive hormone analyses			
Anti-Muellerian hormone level decreased		1	0
Blood oestrogen increased		1	0
Dihydrotestosterone decreased		1	0
False negative pregnancy test		2	0
Human chorionic gonadotropin decreased		1	0
Pregnancy test		10	0
Pregnancy test false positive		1	0
Pregnancy test negative		1	0
Reproductive organ and breast imaging prod	edures		
Ultrasound scan vagina normal		1	0
Respiratory and pulmonary function diagnos	tic procedures		
Forced expiratory volume	•	2	0
Forced expiratory volume decreased		1	0
Forced expiratory volume increased		11	0
Forced expiratory volume normal		1	0
Forced vital capacity decreased		1	0
Maximal voluntary ventilation		2	0
Peak expiratory flow rate		1	0
Peak expiratory flow rate decreased		6	0
Pulmonary function test		2	0
Pulmonary function test decreased		2	0
Slow vital capacity		1	0
Total lung capacity decreased		3	0
Respiratory tract and thoracic histopathology	procedures		
Sputum abnormal		2	0
Respiratory tract and thoracic imaging proce	dures		
Chest X-ray		14	0
Computerised tomogram thorax		4	0
Laryngoscopy		1	0
Skeletal and cardiac muscle analyses			
Blood creatine phosphokinase increased		5	0
Myocardial necrosis marker		1	0
Myocardial necrosis marker increased		1	0
Troponin		2	0
Troponin I increased		1	0
Troponin T		1	0
Troponin T increased		1	0
Therapeutic drug monitoring analyses		1	J
Analgesic drug level		17	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		_Total_	<u>Fatal</u>
Investigations Investigations cont'd			
Analgesic drug level increased		1	0
Analgesic drug level therapeutic		1	0
Anticoagulation drug level above therapeut		3	0
Anticoagulation drug level below therapeut	С	3	0
Anticoagulation drug level increased		1	0
Antidepressant drug level decreased		1	0
Thyroid analyses			
Anti-thyroid antibody		1	0
Thyroid function test abnormal		1	0
Thyroxine		1	0
Thyroxine abnormal		1	0
Tri-iodothyronine decreased		6	0
Tissue enzyme analyses NEC			
Blood lactate dehydrogenase		1	0
Blood lactate dehydrogenase increased		1	0
Lactate dehydrogenase urine increased		1	0
Toxicology laboratory analyses			
Blood aluminium		1	0
Blood cannabinoids		1	0
Blood carbon monoxide increased		1	0
Blood heavy metal test		1	0
Blood lead		1	0
Drug screen positive		3	0
Urinalysis NEC			
Blood urine		27	0
Blood urine present		61	0
Cells in urine		2	0
Crystal urine		3	0
Medication crystals in urine present		1	0
Protein urine present		1	0
Red blood cells urine		1	0
Urea urine increased		1	0
Urine analysis		1	0
Urine analysis abnormal		12	0
Urine analysis normal		3	0
pH urine		8	0
pH urine decreased		2	0
pH urine increased		2	0
Urinary tract function analyses NEC			
Urine output		41	0
Urine output decreased		18	0
Urine output increased		10	0
Urinary tract imaging procedures			
Cystoscopy		1	0
Vascular auscultatory investigations			
Abdominal bruit		1	0
Carotid bruit		1	0
Vascular imaging procedures NEC			
Venogram		1	0
Vascular tests NEC (incl blood pressure)			
Blood pressure abnormal		4	0
Blood pressure decreased		69	0
Blood pressure diastolic decreased		1	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
Investigations Investigations cont'd		
Blood pressure diastolic increased	3	
Blood pressure increased	249	0
Blood pressure measurement	83	0
Blood pressure normal	4	. 0
Blood pressure systolic		0
Blood pressure systolic increased	5	0
Capillary nail refill test		0
Virus identification and serology		
Coronavirus test	38	0
Cytomegalovirus test	1	0
HIV antibody negative	2	1
Hepatitis B core antibody positive	1	0
Herpes virus test	1	0
Human papilloma virus test positive	1	0
SARS-CoV-1 test positive	1	ő
SARS-CoV-2 antibody test	5	
SARS-CoV-2 antibody test negative	13	
SARS-CoV-2 antibody test positive	3	
SARS-CoV-2 test	18	1
SARS-CoV-2 test false negative	3	
SARS-CoV-2 test false positive	3	1
SARS-CoV-2 test negative	14	
SARS-CoV-2 test negative	71	1
Viral test	3	
Vitamin analyses		
Blood folate	2	2 0
Blood folate Blood folate decreased	3	1
Vitamin B12 decreased	1	
Vitamin D decreased		1
	2	2 0
Water and electrolyte analyses NEC Blood osmolarity	1	
Volume blood	6	0 0
White blood cell analyses	0	
· · · · · · · · · · · · · · · · · · ·	1	
CD4 lymphocytes decreased Eosinophil count decreased		0
	4	0
Eosinophil count increased	4	
Lymphocyte count		0
Lymphocyte count decreased	4	0
Lymphocyte count increased Mononuclear cell count abnormal	3	
	1	0
Neutrophil count	3	
Neutrophil count decreased	12	2 0
Neutrophil count increased		0
Neutrophil toxic granulation present	1	0
White blood cell count	13	
White blood cell count decreased	22	1
White blood cell count increased	8	
Investigations SOC TOTAL	8701	1

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDR	RA 24.0	
Reaction Name	<u> Total</u>	<u>Fatal</u>
Metabolic disorders		
Appetite disorders		
Appetite disorder	36	0
Decreased appetite	5901	1
Diet refusal	2	<u>.</u> 0
Eating disorder symptom	1	0
Food craving	20	o l
Food refusal	34	
Hyperphagia	7	I
Hypophagia	26	
Increased appetite	50	
Salt craving	4	
Calcium metabolism disorders		
Hypercalcaemia	2	2 0
Hypocalcaemia	2 5	
Tetany	1	Ö
Diabetes mellitus (incl subtypes)		
Diabetes mellitus	74	0
	27	
Diabetes mellitus inadequate control		1
Increased insulin requirement Insulin resistant diabetes	1	0 0
	10	
Type 1 diabetes mellitus	16	
Type 2 diabetes mellitus	2	2 0
Diabetic complications NEC	0.0	
Diabetic ketoacidosis	30	1
Diabetic ketosis	5	
Euglycaemic diabetic ketoacidosis	1	0
Diabetic complications neurological		
Hyperglycaemic hyperosmolar nonketotic syndrome	1	0
Disorders of purine metabolism		_
Gout	113	0
Electrolyte imbalance NEC		
Electrolyte imbalance	3	1
Fluid imbalance		0
Hyperosmolar state	1	1
Fat soluble vitamin deficiencies and disorders		
Vitamin D deficiency	5	0
Fluid intake decreased		
Fluid intake reduced	10	0
Fluid intake increased		
Polydipsia	13	0
Food malabsorption and intolerance syndromes (excl sugar intole	rance)	
Alcohol intolerance	7	0
Food intolerance	10	0
Gluten sensitivity	3	0
Histamine intolerance	3	0
General nutritional disorders NEC		
Abnormal loss of weight	42	2 o
Abnormal weight gain	19	
Cachexia	1	0
Feeding disorder	170	
Food aversion	53	1
Neonatal insufficient breast milk syndrome	3	I
Obesity	1	1

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Overweight	2	0
Poor feeding infant	9	0
Starvation	1	0
Underweight	1	0
Weight loss poor	2	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	124	0
Insulin resistance	8	0
Metabolic syndrome	1	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Hyperinsulinaemic hypoglycaemia	1	0
Hypoglycaemia	89	0
Hypoglycaemia unawareness	3	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	6	0
Iron excess		
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Lipoedema	1 1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1 1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	1 1	0
Ketosis	4	0
Lactic acidosis	2	0
Metabolic acidosis	9	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	3	0
Phosphorus metabolism disorders		
Hypophosphataemia	2	0
Potassium imbalance		
Hyperkalaemia	6	1
Hypokalaemia	4	0
Protein metabolism disorders NEC		
Hypoalbuminaemia	1	0
Sodium imbalance		
Hypernatraemia	2	0
Hyponatraemia	19	0
Hyponatraemic syndrome	3	1
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	6	0
Total fluid volume decreased		
Dehydration Dehydration	598	0
Hypovolaemia	1	0
Total fluid volume increased		Ū
Fluid overload	6	0
Fluid retention	52	1

Name: COVID-19 AstraZeneca Vaccine Analysis Print

n Date: 28-May-2021 Data Lock Date: 26-May-2021 19:00:03
eaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0 Report Run Date: 28-May-2021 Earliest Reaction Date: 03-Feb-1921

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Vitamin deficiencies NEC		
Hypovitaminosis	1	0
Water soluble vitamin deficiencies		
Folate deficiency	3	0
Vitamin B12 deficiency	3	0
Metabolic disorders SOC TOTAL	7686	7

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Reaction Name	Tota	<u>aL</u>	Fatal
Muscle & tissue disorders			
Arthropathies NEC			
Arthritis	3	36	0
Arthritis enteropathic		1	0
Arthropathy		24	0
Autoimmune arthritis		7	0
Haemarthrosis		7	0
Oligoarthritis		1	0
Palindromic rheumatism		3	0
Polyarthritis		14	0
Rheumatic fever		5	0
Sacroiliitis		3	0
Bone disorders NEC		J	J
Bone disorder		2	0
Bone erosion		4	0
Bone loss		1	0
		1	0
Jaw disorder		4	0
Medial tibial stress syndrome		7	0
Osteitis		6	0
Osteonecrosis of jaw		3	0
Spinal disorder		1	0
Bone related signs and symptoms			
Bone pain	g	21	0
Bone swelling		2	0
Coccydynia		4	0
Pain in jaw	5	10	0
Pubic pain		1	0
Spinal pain	2	07	0
Bursal disorders			
Bursitis		93	0
Cartilage disorders			
Chondritis		1	0
Chondropathy		1	0
Costochondritis		47	0
Connective tissue disorders NEC			
Connective tissue disorder		2	0
Mixed connective tissue disease		1	0
Morphoea		1	0
Polymyalgia rheumatica		54	0
Reynold's syndrome		5	0
Scleroderma		2	0
Sjogren's syndrome		1	0
Crystal arthropathic disorders			
Chondrocalcinosis pyrophosphate		1	0
Gouty tophus		1	0
Epiphyseal disorders		·	
Epiphyses premature fusion		1	0
Extremity deformities		•	
Finger deformity		3	0
Foot deformity		1	0
Hand deformity		3	0
Limb deformity		6	0
		2	0
Wrist deformity			U
Fractures NEC			

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Reaction Name		Total	Fatal
Muscle & tissue disorders e & tissue disorders co	nt'd		
Osteoporotic fracture		1	0
Intervertebral disc disorders NEC			
Intervertebral disc degeneration		1	0
Intervertebral disc protrusion		3	0
Joint related disorders NEC			
Ankle impingement		1	0
Femoroacetabular impingement		2	0
Joint ankylosis		1	0
Joint contracture		1	0
Joint instability		2	0
Joint laxity		4	0
Joint lock		39	0
Ligament laxity		1	0
Patellofemoral pain syndrome		4	0
Periarthritis		232	0
Rotator cuff syndrome		50	0
Temporomandibular joint syndrome		15	0
Joint related signs and symptoms			
Arthralgia		19846	0
Jaw clicking		4	0
Joint effusion		3	0
Joint noise		36	0
Joint range of motion decreased		3	0
Joint stiffness		355	0
Joint swelling		666	0
Joint vibration		3	0
Joint warmth		26	0
Loose body in joint		1	0
Ligament disorders			
Ligament pain		10	0
Lupus erythematosus (incl subtypes)			
Lupus-like syndrome		1	0
Systemic lupus erythematosus		27	0
Metabolic bone disorders			
Dwarfism		1	0
Osteopenia		1	0
Osteoporosis		10	0
Muscle infections and inflammations			
Myositis		28	0
Polymyositis		1	0
Muscle pains			
Fibromyalgia		219	0
Myalgia		24331	0
Myalgia intercostal		2	0
Myofascial pain syndrome		19	0
Muscle related signs and symptoms NEC			
Haematoma muscle		2	0
Muscle atrophy		20	0
Muscle discomfort		10	0
Muscle disorder		5	0
Muscle fatigue		837	0
Muscle haemorrhage		3	0
Muscle mass		5	0

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Reaction Name	Total_	<u> Fatal</u>
Muscle & tissue disorders le & tissue disorders cont'd		
Muscle oedema	2	2 0
Muscle spasms	2426	0
Muscle swelling	24	
Muscle tightness	157	1
Muscle twitching	396	0
Muscle tone abnormalities		
Muscle rigidity	46	
Nuchal rigidity	14	0
Torticollis	8	0
Trismus	49	0
Muscle weakness conditions		
Muscular weakness	1648	0
Musculoskeletal and connective tissue conditions I	NEC	
Back disorder	1	0
Extremity contracture	1	0
Infantile back arching	1	0
Limb mass		0
Mandibular mass	1	0
Mastication disorder	3	0
Mobility decreased	95	0
Muscle contracture	2	2 0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	1891	0
Posture abnormal	1	0
Somatic dysfunction	1	0
Weight bearing difficulty	6	
Musculoskeletal and connective tissue deformities	of skull. face and	
buccal cavity	,	
Facial asymmetry	2	2 0
Head deformity	1	0
Musculoskeletal and connective tissue infections a	nd inflammations NEC	
Connective tissue inflammation		2 0
Dactylitis	2	2 0
Fasciitis	1	0
Plantar fasciitis	6	0
Musculoskeletal and connective tissue pain and dis	scomfort	
Amplified musculoskeletal pain syndrome	1	0
Back pain	4977	o (
Flank pain	65	0
Growing pains	8	0
Limb discomfort	1932	2 0
Musculoskeletal chest pain	357	rl o
Musculoskeletal discomfort	109	
Musculoskeletal pain	58	0
Neck pain	2575	
Pain in extremity	18331	1
Rheumatic disorder	16	
Myopathies		
Compartment syndrome	3	0
Muscle necrosis		Ö
Myopathy	4	
Rhabdomyolysis	7	1
Osteoarthropathies		

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Reaction Name	<u>To</u>	<u>tal</u>	Fatal
Muscle & tissue disorders e & tissue disc	orders cont'd		
Nodal osteoarthritis		1	0
Osteoarthritis		39	0
Spinal osteoarthritis		4	0
Psoriatic arthropathies			
Psoriatic arthropathy		24	0
Rheumatoid arthropathies			
Felty's syndrome		1	0
Juvenile idiopathic arthritis		2	0
Rheumatoid arthritis		127	0
Rheumatoid nodule		1	0
Still's disease		4	0
Soft tissue disorders NEC			
Axillary mass		51	0
Clubbing		1	0
Fistula		1	0
Groin pain		173	0
Neck mass		17	0
Soft tissue disorder		2	0
Soft tissue mass		3	0
Soft tissue swelling		5	0
Spine and neck deformities			
Kyphosis		4	0
Scoliosis		2	0
Spinal stenosis		2	0
Spondyloarthropathies			
Ankylosing spondylitis		27	0
Arthritis reactive		24	0
Axial spondyloarthritis		1	0
Spondylitis		4	0
Synovial disorders			
Synovial cyst		6	0
Synovitis		11	0
Tendon disorders			
Enthesopathy		1	0
Tendon discomfort		3	0
Tendon disorder		5	0
Tendon pain		28	0
Tendonitis		52	0
Tenosynovitis		1	0
Tenosynovitis stenosans		1	0
Trigger finger		18	0
Muscle & tissue disorders SOC TOTAL	. 85	5018	1

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Neoplasms		
Anal canal neoplasms malignant		
Anal cancer	1	0
B-cell lymphomas NEC		
B-cell lymphoma	1	0
Follicular lymphoma	1	0
Bladder neoplasms malignant		
Bladder cancer	1	0
Bone neoplasms malignant (excl sarcomas)		
Bone cancer	1	0
Breast and nipple neoplasms benign		
Benign breast neoplasm	1	0
Breast and nipple neoplasms malignant		
Breast cancer	38	0
Breast cancer male	2	0
Breast cancer metastatic	1	0
Breast cancer stage III	2	0
Intraductal proliferative breast lesion	1	0
Cardiovascular neoplasms benign		
Haemangioma	2	0
Central nervous system neoplasms malignant NEC		
Brain cancer metastatic	2	0
Brain neoplasm malignant	1	0
Cervix neoplasms malignant		
Cervix carcinoma	1	0
Colorectal neoplasms malignant		
Colon cancer	1	0
Colorectal cancer	1	0
Endocrine neoplasms benign NEC		
Pituitary tumour benign	2	0
Endocrine neoplasms malignant and unspecified NEC		
Neuroendocrine tumour	1	0
Endometrial neoplasms malignant		
Endometrial cancer	2	0
Gastrointestinal neoplasms benign NEC		
Gastrointestinal tract adenoma	1	0
Gastrointestinal neoplasms malignant NEC		
Gastrointestinal carcinoma	2	0
Haematologic neoplasms NEC		
Systemic mastocytosis	1	0
Hepatic neoplasms malignant		
Hepatocellular carcinoma	3	0
Hepatoblastomas		
Hepatoblastoma	1	0
Hodgkin's disease NEC		
Hodgkin's disease	1	0
Leiomyosarcomas		
Pleomorphic leiomyosarcoma	1	0
Leukaemias NEC		
Leukaemia	1	0
Leukaemia recurrent	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	6	0
Leukaemias chronic myeloid		

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

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Reaction Name	Total	<u>Fatal</u>
Neoplasms Neoplasms cont'd		
Ovarian cancer stage IV	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	3	0
Paranasal sinus and nasal cavity neoplasms malignant and unspecified		
Nasal cavity cancer	1	0
Paraneoplastic syndromes NEC		
Paraneoplastic syndrome	1	0
Penile neoplasms malignant		
Penile cancer	1	0
Plasma cell myelomas		
Plasma cell myeloma	2	0
Plasmacytoma	1	0
Prostatic neoplasms malignant		
Prostate cancer	7	0
Renal neoplasms malignant	,	U
Clear cell renal cell carcinoma	3	0
Metastatic renal cell carcinoma	1	0
Renal cancer	1	0
	I	U
Respiratory tract and pleural neoplasms malignancy unspecified NEC	1	0
Maxillofacial sinus neoplasm	I	U
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	4	0
	4	0
Lung cancer metastatic		0
Lung neoplasm malignant	9	0
Throat cancer	1	0
Salivary gland neoplasms malignant	4	_
Salivary gland cancer stage 0	1	0
Salivary gland cancer stage III	1	0
Skin melanomas (excl ocular)		_
Acral lentiginous melanoma stage III	1	0
Malignant melanoma	2	0
Malignant melanoma in situ	1	0
Skin neoplasms benign		
Acrochordon	2	0
Anogenital warts	1	0
Haemangioma of skin	10	0
Melanocytic naevus	2	0
Skin papilloma	14	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	1	0
Skin cancer	2	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Knuckle pads	1	0
Lipoma	4	0
Uterine neoplasms benign		
Uterine leiomyoma	4	0
Uterine neoplasms malignant NEC	7	U
Uterine cancer	1	0
Neoplasms SOC TOTAL	248	4
NEODIGOLIS OOC LOTAL	248	4

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Reaction Name	<u>Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	20	0
Extensor plantar response	2	0
Hyperreflexia	5	0
Hyporeflexia	16	0
Poor sucking reflex	2	0
Reflexes abnormal	1	0
Abnormal sleep-related events		
Sleep paralysis	22	0
Absence seizures		
Petit mal epilepsy	28	0
Acute polyneuropathies		
Acute motor axonal neuropathy	3	0
Acute polyneuropathy	2	0
Guillain-Barre syndrome	270	4
Miller Fisher syndrome	15	0
Subacute inflammatory demyelinating polyneuropathy	1	0
Auditory nerve disorders		
Acoustic neuritis	1	0
Autonomic nervous system disorders		
Autonomic nervous system imbalance	10	0
Horner's syndrome	1	0
Orthostatic intolerance	3	0
Central nervous system aneurysms and dissections		
Carotid artery dissection	1	0
Intracranial aneurysm	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia haemorrhage	3	0
Basal ganglia stroke	1	0
Basilar artery thrombosis	2	0
Brain stem haemorrhage	2	0
Brain stem infarction	2 2	2
Brain stem stroke	3	2
Carotid artery occlusion	2	0
Carotid artery thrombosis	8	0
Cerebellar haemorrhage	4	0
Cerebellar infarction	4	0
Cerebellar stroke	9	0
Cerebral artery embolism	8	0
Cerebral artery occlusion	3	0
Cerebral artery thrombosis	8	0
Cerebral haematoma	12	1
Cerebral haemorrhage	127	33
Cerebral infarction	64	3
Cerebral ischaemia	3	0
Cerebral thrombosis	28	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	791	33
Embolic stroke	17	0
Haemorrhage intracranial	44	7
Haemorrhagic cerebral infarction	2	1
Haemorrhagic stroke	28	4
Haemorrhagic transformation stroke	6	

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Reaction Name		<u>Total</u>	<u>Fatal</u>
Nervous system disorders system disorders	cont'd		
Internal capsule infarction		1	0
Intracranial haematoma		6	1
Intraventricular haemorrhage		6	0
Ischaemic cerebral infarction		2	0
Ischaemic stroke		91	3
Lacunar infarction		4	0
Lacunar stroke		19	0
Spinal cord haematoma		2	0
Subarachnoid haemorrhage		81	4
Thalamus haemorrhage		6	0
Thrombotic stroke		9	0
Vertebral artery occlusion		1	0
Central nervous system inflammatory disor	ders NEC		
Arachnoiditis		2	0
Central nervous system inflammation		10	0
Neurosarcoidosis		3	0
Central nervous system vascular disorders	NEC		
Brain hypoxia		1	1
Carotid artery stenosis			0
Central nervous system vasculitis		3	0
Cerebral amyloid angiopathy		2 3 2 2 1	0
Cerebral congestion		2	0
Cerebral microhaemorrhage		1	0
Cerebral small vessel ischaemic disease			0
Cerebral vasoconstriction		2 1	0
Cerebrovascular disorder		3	0
Internal carotid artery deformity		1	0
Reversible cerebral vasoconstriction sync	Irome	2	0
Cerebrovascular venous and sinus thrombo			
Cerebral venous sinus thrombosis		166	19
Cerebral venous thrombosis		32	4
Superior sagittal sinus thrombosis		23	
Transverse sinus thrombosis		4	2
Cervical spinal cord and nerve root disorde	rs		
Cervical radiculopathy		4	0
Cervicobrachial syndrome		5	0
Choreiform movements		J	Ĭ
Chorea		3	0
Choreoathetosis		1	0
Sydenham's chorea		1	0
Chronic polyneuropathies			Ĭ
Chronic inflammatory demyelinating polyi	adiculoneuropathy	2	0
Demyelinating polyneuropathy	adiodioniodropatry	2 6	0
Diabetic neuropathy		2	0
Coma states		_	· ·
Coma		12	0
Diabetic coma		3	0
Hypoglycaemic coma		1	0
Coordination and balance disturbances		1	U
Ataxia		27	0
Balance disorder		671	0
Cerebellar ataxia		1	0
Coordination abnormal		93	0
Coordination abriornial		90	U

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Reaction Name		<u>Total</u>	<u>Fatal</u>
Nervous system disorders us system disorders c	ont'd		
Dysdiadochokinesis		1	0
Dysstasia		84	0
Hand-eye coordination impaired		1	0
Nystagmus		17	0
Cortical dysfunction NEC			
Alexia		4	0
Aphasia		106	0
Apraxia		1	0
Dysgraphia		4	0
Dyslexia		2	0
Dyspraxia		l 4	0
Neurologic neglect syndrome		3	0
Visuospatial deficit		2	0
Cranial nerve disorders NEC			
Cranial nerve disorder		2	0
Cranial nerve paralysis		2 1	0
Neurovascular conflict		1	0
Paresis cranial nerve		2	0
Dementia (excl Alzheimer's type)			
Dementia		17	0
Dementia with Lewy bodies		1	0
Frontotemporal dementia		1	0
Senile dementia		1	0
Vascular dementia		4	0
Demyelinating disorders NEC		·	·
Acute disseminated encephalomyelitis		7	0
Demyelination		13	0
Neuromyelitis optica spectrum disorder		1	0
Disturbances in consciousness NEC			·
Altered state of consciousness		10	0
Consciousness fluctuating		4	0
Depressed level of consciousness		74	0
Lethargy		4218	0
Loss of consciousness		886	0
Postictal state		1	0
Sedation		11	0
Somnolence		1612	1
Stupor		8	0
Syncope		2138	0
Disturbances in sleep phase rhythm		2100	· ·
Advanced sleep phase		1	0
Circadian rhythm sleep disorder		5	0
Irregular sleep phase		1	0
Irregular sleep wake rhythm disorder		1	0
Dyskinesias and movement disorders NEC		'	U
Akathisia		10	0
Ballismus		10	0
Bradykinesia		25	0
Clumsiness		40	0
Dyskinesia		95	0
		18	
Extrapyramidal disorder		2	0
Fine motor delay		11	0
Fine motor skill dysfunction		11	U

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Reaction Name	To	<u>otal</u>	Fatal
Nervous system disorders us system disorders	cont'd		
Hyperkinesia		26	0
Hypokinesia		50	0
Meige's syndrome		1	0
Motor dysfunction		14	0
Movement disorder		68	0
Psychomotor hyperactivity		32	0
Dystonias			_
Dystonia		16	0
Dystonic tremor		3	0
Opisthotonus		4	0
Writer's cramp		1	0
Encephalitis NEC		- 1	U
Noninfective encephalitis		4	0
Encephalopathies NEC		4	U
		2	0
Autoimmune encephalopathy		3	0
Encephalopathy		5	0
Hypoxic-ischaemic encephalopathy		1	0
Posterior reversible encephalopathy sync	rome	2	0
Encephalopathies toxic and metabolic			
Hepatic encephalopathy		2	0
Eye movement disorders			
IIIrd nerve disorder		1	0
IIIrd nerve paralysis		5	0
Microvascular cranial nerve palsy		2	0
VIth nerve paralysis		7	0
Facial cranial nerve disorders			
Bell's palsy		363	0
Facial nerve disorder		4	0
Facial paralysis		212	0
Facial paresis		114	0
Facial spasm		26	0
Oculofacial paralysis		1	0
Generalised tonic-clonic seizures			
Generalised tonic-clonic seizure		65	0
Headaches NEC			
Cervicogenic headache		5	0
Cluster headache		605	0
Cold-stimulus headache		65	0
Drug withdrawal headache		15	0
Exertional headache		10	0
External compression headache		4	0
Headache	7	1866	4
Medication overuse headache	,	14	0
New daily persistent headache		18	0
		16	0
Occipital neuralgia		10	0
Ophthalmoplegic migraine		1	0
Post-traumatic headache		3	0
Primary cough headache	1	- 2	0
Primary headache associated with sexua	i activity	11	0
Sinus headache		842	0
Tension headache		1258	0
Thunderclap headache		40	0
Vascular headache		67	0

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Reaction Name		<u>Total</u>	Fatal
Nervous system disorders co	ont'd		
Hydrocephalic conditions			
Hydrocephalus		9	0
Hypoglossal nerve disorders			
Tongue paralysis		5	0
Increased intracranial pressure disorders			
Brain compression		2	0
Brain oedema		22	1
Cerebrospinal fluid circulation disorder		3	0
Idiopathic intracranial hypertension		5	0
Intracranial pressure increased		19	0
Intellectual disabilities			
Intellectual disability		9	0
Lumbar spinal cord and nerve root disorders			
Lumbar radiculopathy		2	0
Sciatica		150	0
Memory loss (excl dementia)			
Amnesia		235	0
Memory impairment		219	0
Transient global amnesia		16	0
Meningitis NEC			
Meningitis noninfective		1	0
Mental impairment (excl dementia and mem	ory loss)		
Cognitive disorder	-	129	1
Disturbance in attention		538	0
Judgement impaired		3	0
Mental impairment		101	0
Migraine headaches			
Basilar migraine		4	0
Hemiplegic migraine		28	0
Migraine		6209	0
Migraine with aura		289	0
Migraine without aura		39	0
Ophthalmic migraine		9	0
Retinal migraine		57	0
Status migrainosus		3	0
Typical aura without headache		3 13	0
Vestibular migraine		21	0
Mixed cranial nerve disorders			
Bulbar palsy		1	0
Mononeuropathies			
Carpal tunnel syndrome		20	0
Cubital tunnel syndrome		1	0
Diabetic mononeuropathy		1	0
Meralgia paraesthetica		2	0
Mononeuritis		2 2 2	0
Mononeuropathy		2	0
Nerve compression		36	0
Peroneal nerve palsy			0
Piriformis syndrome		2	0
Radial nerve palsy		9 2 2 3 1	0
Sciatic nerve neuropathy		3	0
Ulnar nerve palsy		1	0
Ulnar neuritis		3	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Nervous system disorders co	ont'd		
Ulnar tunnel syndrome		1	0
Motor neurone diseases			
Motor neurone disease		1	0
Multiple sclerosis acute and progressive			
Band sensation		4	0
Multiple sclerosis		50	0
Multiple sclerosis relapse		38	0
Relapsing multiple sclerosis		1	0
Uhthoff's phenomenon		4	0
Muscle tone abnormal			
Hypertonia		2	0
Hypotonia		31	0
Serotonin syndrome		1	0
Stiff leg syndrome		7	0
Myelitis (incl infective)			
Myelitis transverse		61	0
Narcolepsy and hypersomnia			
Cataplexy		1	0
Hypersomnia		164	0
Narcolepsy		13	0
Nervous system cysts and polyps			
Pineal gland cyst		1	0
Nervous system disorders NEC			
Brain stem syndrome		2	0
Cerebral disorder		1	0
Nervous system disorder		34	0
Neurotoxicity		1	0
Psychomotor skills impaired		4	0
Neurologic visual problems NEC			
Hemianopia		7	0
Hemianopia homonymous		1	0
Tunnel vision		14	0
Neurological signs and symptoms NEC			
Agitation neonatal		1	0
Dizziness		19039	0
Dizziness exertional		80	0
Dizziness postural		1891	1
Drooling		17	0
Exaggerated startle response		3	0
Fontanelle bulging		3	0
Head discomfort		531	0
Hyporesponsive to stimuli		2	0
Inability to crawl		1	0
Infant irritability		5	0
Intracranial hypotension		5 2 2	0
Meningism		2	0
Myoclonus		24	0
Neurological decompensation		4	0
Neurological symptom		83	0
Patient elopement		1	0
Persistent postural-perceptual dizziness		27	0
Pleocytosis		3	
Presyncope		521	0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		_Total_	<u>Fatal</u>
Nervous system disorders us system disorders co	ont'd		
Sensory overload		10	0
Slow response to stimuli		5	0
Tongue biting		7	0
Unresponsive to stimuli		79	0
Neuromuscular disorders NEC			
Muscle contractions involuntary		27	0
Muscle spasticity		20	0
Neuromuscular pain		6	0
Neuromyopathy		3	0
Neuromyotonia		1	0
Neuromuscular junction dysfunction		'	0
Myasthenia gravis		9	0
Myasthenia gravis crisis		3	0
Olfactory nerve disorders		J	J
Anosmia		244	0
		10	0
Hyposmia Parosmia		323	0
		323	U
Optic nerve disorders NEC		25	0
Optic neuritis		35	0
Paraesthesias and dysaesthesias			_
Anaesthesia		3	0
Burning feet syndrome		21	0
Burning sensation		707	0
Burning sensation mucosal		3	0
Dysaesthesia		7	0
Formication		54	0
Hand-arm vibration syndrome		1	0
Hemianaesthesia		3	0
Hemiparaesthesia		2	0
Hyperaesthesia		232	0
Hypoaesthesia		4376	0
Lhermitte's sign		1	0
Paraesthesia		7382	0
Paralysis and paresis (excl cranial nerve)			
Diplegia		23	0
Hemiparesis		75	0
Hemiplegia		23	0
Monoparesis		74	0
Monoplegia		99	0
Paralysis		239	0
Paraparesis		6	0
Paraplegia		2	0
Paresis		5	0
Peripheral nerve palsy		1	0
Postictal paralysis		1	0
Quadriplegia		3	0
Parkinson's disease and parkinsonism			_
Freezing phenomenon		142	0
Parkinson's disease		15	0
Parkinsonism		10	0
Reduced facial expression		6	0
Vascular parkinsonism		1	0
Partial complex seizures		1	U
i aruai corriptex seizures			

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	<u>Total</u>	Fatal
Nervous system disorders us system disorders o	cont'd	
Dreamy state	18	3 0
Focal dyscognitive seizures		5 0
Temporal lobe epilepsy		3 0
Partial simple seizures NEC		
Autonomic seizure		1 0
Simple partial seizures	4	4 ol
Peripheral neuropathies NEC		
Autoimmune neuropathy		2 0
Axonal neuropathy		1 0
Ischaemic neuropathy		1 0
Neuralgic amyotrophy		4 ol
Neuritis	8	3l ol
Neuropathy peripheral	149	el ol
Peripheral motor neuropathy		1 0
Peripheral sensorimotor neuropathy		2 0
Peripheral sensory neuropathy	1;	3 0
Polyneuropathy		3 0
Small fibre neuropathy		2 0
Thoracic outlet syndrome		1 ol
Seizures and seizure disorders NEC		
Alcoholic seizure		1l ol
Atonic seizures	10	
Change in seizure presentation		5 0
Clonic convulsion		3 0
Drug withdrawal convulsions		2 0
Epilepsy	224	
Epileptic aura		
Febrile convulsion	82	2 0
Migraine-triggered seizure	· ·	1 ol
Myoclonic epilepsy		4l ol
Partial seizures	46	6 0
Psychogenic seizure		5 0
Seizure	1003	3 2
Seizure anoxic		3 0
Seizure cluster		4 0
Seizure like phenomena		2 0
Status epilepticus	11.	1 3
Tonic clonic movements		2 0
Tonic convulsion	3.	1 ol
Sensory abnormalities NEC		
Ageusia	898	3 0
Allodynia	53	
Aura	20	
Central pain syndrome		2 0
Complex regional pain syndrome		3 0
Dysgeusia	1769	
Electric shock sensation	69	
Hypogeusia	.	
Intercostal neuralgia		
Loss of proprioception	:	3 0
Neuralgia Neuralgia	1009	
Persistent genital arousal disorder	1000	1 0
Phantom limb syndrome	17	

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name	<u>To</u>	<u>tal</u>	Fatal
Nervous system disorders us system disorders co	ont'd		
Post herpetic neuralgia		9	0
Restless arm syndrome		11	0
Restless legs syndrome		315	0
Sensory disturbance		90	0
Sensory loss		159	0
Taste disorder		434	0
Vibratory sense increased		1	0
Visual perseveration		1	0
Sleep disturbances NEC			J
Microsleep		2	0
Sleep deficit		42	0
Speech and language abnormalities		72	J
Dysarthria Dysarthria		295	0
Incoherent		14	0
Language disorder		2	0
Muscle tension dysphonia		1	0
Slow speech		24	0
Speech disorder		58	0
Spinal cord and nerve root disorders NEC		- 30	U
Cauda equina syndrome		4	0
· · ·			0
Myelopathy Radicular pain		3	0
Radicular pain Radiculitis brachial		1	_
		11	0
Radiculopathy		2	0
Spinal cord disorder		3	0
Structural brain disorders NEC		40	4
Brain injury		18	1
Cerebral mass effect		5	0
Intracranial mass		3	0
White matter lesion		1	0
Transient cerebrovascular events		000	0
Transient ischaemic attack		339	0
Tremor (excl congenital)		_	0
Action tremor		2	0
Asterixis		1	0
Essential tremor		5	0
Head titubation		15	0
Intention tremor		1	0
Postural tremor		1	0
Resting tremor		5	0
Tremor		8913	3
Trigeminal disorders			
Facial neuralgia		28	0
Numb chin syndrome		2	0
Trigeminal nerve disorder		3	0
Trigeminal neuralgia		65	0
Trigeminal neuritis		2	0
Trigeminal palsy		1	0
Vagus nerve disorders			
Vagus nerve paralysis		1	0
Vocal cord paralysis		1	0
Vertigos NEC			
Vertigo CNS origin		2	0

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Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Nervous system disorders SOC TOTAL	149957	146

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Pregnancy conditions		
Abortions spontaneous		
Abortion spontaneous	70	1
Foetal complications NEC		
Foetal disorder	1	0
Foetal hypokinesia	1	0
Foetal position and presentation abnormalities		
Face presentation	2	0
High risk pregnancies		
Pregnancy with young maternal age	1	0
Labour onset and length abnormalities		
Precipitate labour	1	0
Premature labour	3	0
Premature rupture of membranes	1	0
Prolonged labour	1	0
Maternal complications of labour NEC		
Uterine contractions abnormal	1	0
Uterine hypertonus	1	0
Maternal complications of pregnancy NEC		
Ectopic pregnancy	3	0
Hyperemesis gravidarum	2	0
Morning sickness	34	0
Pelvic girdle pain	1	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Pregnancy	19	0
Uterine contractions during pregnancy	1	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	6	0
Stillbirth and foetal death		
Stillbirth	3	1
Umbilical cord complications		
Umbilical cord abnormality	1	0
Unintended pregnancies		
Pregnancy after post coital contraception	4	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	3	0
Unintended pregnancy	4	0
Pregnancy conditions SOC TOTAL	169	2

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Report Run Date: 28-May-2021
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Reaction Name	Total	Fatal
Device electrical issues		
Device electrical impedance issue	1	0
Device incompatibility issues		
Patient-device incompatibility	1	0
Device issues NEC		
Device issue	2	0
Device leakage	2	0
Device malfunction events NEC		
Oversensing	24	0
Stent malfunction	1	0
Thrombosis in device	34	0
Undersensing	3	0
Device physical property and chemical issues		
Needle issue	7	0
Syringe issue	1	0
Manufacturing facilities and equipment issues		
Manufacturing equipment issue	1	0
Product contamination and sterility issues		
Product contamination	1	0
Product distribution and storage issues		
Product temperature excursion issue	2	0
Product label issues		
Product barcode issue	1	0
Product label issue	2	0
Product packaging issues		
Product container issue	1	0
Product physical issues		
Product colour issue	1	0
Product leakage	1	0
Product odour abnormal	1	0
Product physical issue	1	0
Product taste abnormal	7	0
Product quality issues NEC		
Product origin unknown	2	0
Product quality issue	1	0
Suspected product quality issue	2	0
null SOC TOTAL	100	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	<u> Total </u>	<u>Fatal</u>
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	14	0
Breath holding	3	0
Staring	8	0
Abnormal food elimination		
Self-induced vomiting	1	0
Adjustment disorders		
Adjustment disorder with depressed mood	5	0
Adjustment disorder with mixed anxiety and depressed mood	1	0
Affect alterations NEC		
Affect lability	9	0
Constricted affect	5	0
Flat affect	10	0
Inappropriate affect	15	0
Amnestic symptoms		
Paramnesia	4	0
Anxiety disorders NEC		
Anxiety disorder	2	0
Generalised anxiety disorder	2	0
Neurosis	1	0
Anxiety symptoms		
Agitation	171	0
Anxiety	841	0
Immunisation anxiety related reaction	1	0
Nervousness	529	0
Stress	89	0
Tension	56	0
Attention deficit and disruptive behaviour disorders		
Attention deficit hyperactivity disorder	13	0
Behaviour and socialisation disturbances		
Aggression	10	0
Asocial behaviour	1	0
Aversion	1	0
Disinhibition	1	0
Impatience	2	0
Indifference	8	0
Paranoia	33	0
Personality change	5	0
Social avoidant behaviour	4	0
Soliloquy	3	0
Violence-related symptom	3	0
Bipolar disorders		
Bipolar I disorder	6	0
Bipolar disorder	3	0
Cognitive and attention disorders and disturbances NEC		
Change in sustained attention	1	0
Daydreaming	12	0
Distractibility	1	0
Mental fatigue	393	0
Communications disorders		
Communication disorder	3	0
Mutism	3	0
Speech sound disorder	2	0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	<u>Fatal</u>
Psychiatric disordersPsychiatric disorders cont'd		
Confusion and disorientation		
Confusional state	1681	1
Disorientation	616	0
Decreased physical activity levels		
Catatonia	2	0
Deliria		
Delirium	435	0
Delirium febrile	3	I
Delusional disorders		
Alice in wonderland syndrome	3	0
Delusional symptoms		
Delusion	38	0
Delusion of parasitosis	1	0
Mixed delusion	1	0
Thought withdrawal	1	0
Depressive disorders		
Agitated depression	3	0
Depression	449	
Depression suicidal	13	
Major depression	19	
Mixed anxiety and depressive disorder	1	Ö
Dissociative states		
Depersonalisation/derealisation disorder	15	0
Dissociation	58	
Dissociative amnesia	1	o o
Dissociative disorder	1	Ö
Disturbances in initiating and maintaining sleep		Ĭ
Initial insomnia	33	0
Insomnia	2644	
Middle insomnia	69	
Terminal insomnia	8	
Dyssomnias		
Dyssomnia	4	0
Poor quality sleep	587	Ö
Eating disorders NEC	00.	Ŭ
Eating disorder	6	0
Emotional and mood disturbances NEC	J	Ĭ
Anger	65	0
Dysphoria	2	
Emotional disorder	79	
Emotional distress	60	
Emotional poverty	2	
Euphoric mood	57	
Frustration tolerance decreased	4	ő
Irritability	255	
Mood altered	58	
Factitious disorders	30	"
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Acrophobia	1	^
Agoraphobia	3	0 0
Fear	29	
Fear of death	13	
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Farliest Reaction Date: 03-Feb-1921

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: I	MedDRA 24.0	
Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric} disorders cont'd		
Fear of disease	2	0
Fear of eating	1	0
Fear of falling	3 2	0
Fear of injection	2	0
Fear of open spaces	1	0
Performance fear	1	0
Phobia	2	0
Phonophobia	3	0
Fluctuating mood symptoms		
Mood swings	63	0
Hallucinations (excl sleep-related)		
Hallucination	833	0
Hallucination, auditory	38	0
Hallucination, olfactory	7	0
Hallucination, tactile	1	0
Hallucination, visual	48	0
Hallucinations, mixed	7	0
Impulse control disorders		
İmpulse-control disorder	2	0
Impulsive behaviour	1	
Intermittent explosive disorder	1	0
Increased physical activity levels		
Restlessness	433	0
Infancy, childhood and adolescence psychiatric disorders NE	EC	
Emotional disorder of childhood	1	0
Mental disorders NEC		
Mental disorder	9	0
Mental status changes	3	0
Mental disorders due to a general medical condition NEC		
Mental disorder due to a general medical condition	1	0
Neuropsychiatric symptoms	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	12	0
Depressed mood	481	0
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	16	0
Negative thoughts	8	
Sense of a foreshortened future	1	0
Tearfulness	92	0
Mood alterations with manic symptoms		
Hypomania	1	0
Mania	28	0
Mood disorders NEC		
Affective disorder	2	
Apathy	45	0
Listless	113	0
Mood disorder due to a general medical condition	1	0
Substance-induced mood disorder	1	
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Sleep attacks	1	

Case Series Drug Analysis Print COVID-19 AstraZeneca Vaccine Analysis P

Psychiatric disorders Psychiatric disorders cont'd Obsessive-compulsive disorders and symptoms Body dysmorphic disorder 2 Compulsive shopping 2 Dermatillomania 1 Obsessive thoughts 3 Obsessive-compulsive disorder 1 Orgasmic disorders and disturbances 2 Anorgasmia 2 Female orgasmic disorder 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 1 Limited symptom panic attack 1 Panic disorder 3 Panic disorder 3 Panic attack 241 Panic disorder 3 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 3 Abnormal dreams 320 Abnormal dreams 320 Abnormal percentated event 1 Confusional arousal	Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Obsessive-compulsive disorders and symptoms 2 Body dysmorphic disorder 2 Compulsive shopping 2 Dermatillomania 1 Obsessive thoughts 3 Obsessive-compulsive disorder 1 Orgasmic disorders and disturbances 1 Anorgasmia 2 Female orgasmic disorder 1 Orgasma abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 5 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia	Reaction Name		<u>Total</u>	<u>Fatal</u>
Body dysmorphic disorder	Psychiatric disorders Psychiatric disorders cont'c			
Compulsive shopping 2 Dermatillomania 1 Obsessive thoughts 3 Obsessive-compulsive disorder 1 Orgasmic disorders and disturbances 1 Anorgasmia 2 Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3		toms		
Dermatillomania 1 Obsessive thoughts 3 Obsessive-compulsive disorder 1 Orgasmic disorders and disturbances 2 Anorgasmia 2 Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	Body dysmorphic disorder		2	0
Obsessive thoughts 3 Obsessive-compulsive disorder 1 Orgasmic disorders and disturbances 2 Anorgasmia 2 Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	Compulsive shopping		2	0
Obsessive-compulsive disorder 1 Orgasmic disorders and disturbances 2 Anorgasmia 2 Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	Dermatillomania		1	0
Orgasmic disorders and disturbances 2 Anorgasmia 2 Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	Obsessive thoughts		3	0
Orgasmic disorders and disturbances 2 Anorgasmia 2 Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	Obsessive-compulsive disorder		1	0
Anorgasmia 2 Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3				
Female orgasmic disorder 1 Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 2 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	_		2	0
Orgasm abnormal 1 Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 1 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			1	0
Orgasmic sensation decreased 4 Premature ejaculation 2 Panic attacks and disorders 1 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	<u> </u>		1	0
Premature ejaculation 2 Panic attacks and disorders 1 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			4	0
Panic attacks and disorders 1 Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3	<u> </u>		2	0
Limited symptom panic attack 1 Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			_	
Panic attack 241 Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			1	0
Panic disorder 3 Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			241	0
Panic reaction 30 Paraphilias and paraphilic disorders 2 Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			3	0
Paraphilias and paraphilic disordersFetishism2Parasomnias320Abnormal dreams320Abnormal sleep-related event1Confusional arousal2Exploding head syndrome6Nightmare399Parasomnia1Rapid eye movements sleep abnormal3			30	0
Fetishism 2 Parasomnias 320 Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3				
ParasomniasAbnormal dreams320Abnormal sleep-related event1Confusional arousal2Exploding head syndrome6Nightmare399Parasomnia1Rapid eye movements sleep abnormal3			2	0
Abnormal dreams 320 Abnormal sleep-related event 1 Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			_	
Abnormal sleep-related event Confusional arousal Exploding head syndrome Nightmare Parasomnia Rapid eye movements sleep abnormal 1 1 1 1 1 1 1 1 1 1 1 1 1			320	0
Confusional arousal 2 Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			1	0
Exploding head syndrome 6 Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3			2	0
Nightmare 399 Parasomnia 1 Rapid eye movements sleep abnormal 3				0
Parasomnia 1 Rapid eye movements sleep abnormal 3				
Rapid eye movements sleep abnormal 3			l .	0
				0
i Sieed ineria I 1	Sleep inertia		1	0
Sleep talking 15	·			
Sleep terror 52	•			0
Sleep-related eating disorder 2				0
Somnambulism 8	•			0
Perception disturbances NEC				
Autoscopy 21			21	0
Deja vu 4				0
Delusional perception 2				0
Derealisation 13			13	0
Flashback 2	Flashback			0
Illusion 11			11	0
Pseudohallucination 1				0
Time perception altered 5			5	0
Pervasive developmental disorders NEC				
Autism spectrum disorder 3			3	0
Psychiatric elimination disorders				
Enuresis 45			45	0
Psychiatric symptoms NEC				
Helplessness 2			2	0
Hypervigilance 13				
Psychiatric symptom 5				
Psychological trauma 3				0
Psychotic disorder NEC				
Acute psychosis 3			3	0
Psychotic behaviour 1				0

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	Fatal
Psychiatric disorders Psychiatric disorders of	ont'd		
Psychotic disorder		31	0
Psychotic symptom		1	0
Rebound psychosis		1	0
Schizoaffective and schizophreniform of	lisorders		
Schizoaffective disorder		1	0
Schizophrenia NEC			
Schizophrenia		1	0
Sexual arousal disorders			
Disturbance in sexual arousal		3	0
Sexual desire disorders			
Hypersexuality		1	0
Libido decreased		13	0
Libido increased		5	0
Loss of libido		32	0
Sexual dysfunction NEC			
Genito-pelvic pain/penetration disorde	er	1	0
Sleep disorders NEC			
Sleep disorder		331	0
Sleep disorder due to general medica	ll condition, insomnia type	2	0
Somatic symptom disorders	,		
Conversion disorder		12	0
Habit cough		31	0
Illness anxiety disorder		1	0
Psychogenic tremor		2	0
Somatic symptom disorder		1	0
Speech and language usage disturban	ces		
Disorganised speech		16	0
Logorrhoea		3	0
Pedantic speech		1	0
Poverty of speech		1	0
Verbigeration		1	0
Speech articulation and rhythm disturba	ances		
Dysphemia		22	0
Lack of spontaneous speech		2	0
Stereotypies and automatisms			
Bruxism		28	0
Head banging		32	0
Waxy flexibility		2	0
Stress disorders			
Acute stress disorder		2	0
Burnout syndrome		9	0
Hyperarousal		3	0
Post-traumatic stress disorder		11	0
Substance related and addictive disord	ers		
Alcohol abuse		2	0
Alcohol use disorder		2	0
Alcoholism		3	0
Dependence		1	0
Drug abuse		1	0
Drug dependence		1	0
Substance abuse		1	0
Suicidal and self-injurious behaviour			
Completed suicide		2	2

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Reaction Name	<u>Total</u>	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Intentional self-injury		8 0
Self-injurious ideation		2 0
Suicidal behaviour		3 0
Suicidal ideation	8	6 0
Suicide attempt	1:	3 0
Suicide threat		1 0
Thinking disturbances		
Bradyphrenia	7	7 0
Confabulation		1 0
Impaired reasoning		2 0
Intrusive thoughts		3 0
Morbid thoughts		4 0
Tachyphrenia	2	1 0
Thinking abnormal	2	1 0
Thought blocking		4 0
Tic disorders		
Tic		9 0
Psychiatric disorders SOC TOTAL	1398	5 3

	ersion: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Renal & urinary disorders		
Bladder and urethral symptoms		
Bladder discomfort	6	0
Bladder irritation	6	0
Bladder pain	47	0 ا
Bladder spasm	1	0
Dysuria	64	1
Incontinence	67	
Micturition disorder	3	
Micturition frequency decreased	1	ő
Micturition urgency	90	
Mixed incontinence	1	Ö
Pollakiuria	243	
Urethral pain Urge incontinence	3 2	
	5	
Urinary hesitation		
Urinary incontinence	95	
Urinary retention	62	
Urine flow decreased	10	0
Bladder disorders NEC		
Bladder dilatation	1	0
Bladder disorder	15	
Urinary bladder haemorrhage	8	1
Bladder infections and inflammations		
Cystitis haemorrhagic	1	0
Cystitis interstitial	5	0
Cystitis noninfective	3	0
Lupus cystitis		0
Genital and urinary tract disorders NEC		
Urinary tract disorder	4	. 0
Glomerulonephritis and nephrotic syndrome		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis membranoproliferative	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	3	
Henoch-Schonlein purpura nephritis	3	0
IgA nephropathy	2	o
Nephrotic syndrome	12	
Myoneurogenic bladder disorders		
Automatic bladder	1	0
Bladder dysfunction	3	_
Hypertonic bladder	13	
Loss of bladder sensation	10	
Neurogenic bladder	2	
Nephritis NEC	2	
	1	_
Lupus nephritis		0
Nephritis Tubulginteretitiel peophritis	5	
Tubulointerstitial nephritis	4	
Nephropathies and tubular disorders NEC		_
Nephropathy	2	0
Renal disorders NEC		
Oedematous kidney		
Renal disorder		' 0

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	Fatal
Renal & urinary disorders & urinary disorders con	t'd		
Renal haemorrhage		1	0
Renal failure and impairment			
Acute kidney injury		45	1
Anuria		5	0
Chronic kidney disease		8	0
Oliguria		10	0
Renal failure		17	0
Renal impairment		12	0
Renal injury		4	0
Renal hypertension and related conditions			
Hypertensive nephropathy		1	0
Renal lithiasis			
Nephrolithiasis		10	0
Renal obstructive disorders			
Hydronephrosis		1	0
Renal structural abnormalities and trauma			
Kidney enlargement		1	0
Renal atrophy		2	0
Renal vascular and ischaemic conditions			
Renal artery occlusion		1	0
Renal embolism		1	0
Renal infarct		10	0
Renal vein embolism		1	0
Renal vein occlusion		1	0
Renal vein thrombosis		8	0
Structural and obstructive urethral disorders (excl congenital)		
Urethral spasm	,	1	0
Ureteric disorders NEC			
Ureteral disorder		2	0
Urinary abnormalities			
Chromaturia		87	0
Glycosuria		1	0
Haematuria		50	0
Microalbuminuria		1	0
Proteinuria		7	0
Urine abnormality		17	0
Urine odour abnormal		18	0
Urinary tract signs and symptoms NEC			
Haemorrhage urinary tract		39	0
Nocturia		16	0
Polyuria		25	0
Renal colic		2	0
Renal pain		821	0
Urinary tract discomfort		1	0
Urinary tract pain		11	0
Renal & urinary disorders SOC TOTAL		2053	5

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name	Tota	<u>1</u>	Fatal
Reproductive & breast disorders			
Benign and malignant breast neoplasms			
Breast cyst		5	0
Breast disorders NEC			
Breast disorder		1	0
Breast enlargement		5	0
Breast mass		35	0
Gynaecomastia		6	0
Breast infections and inflammations			
Breast inflammation		2	0
Nipple inflammation		1	0
Breast signs and symptoms			
Breast discharge		8	0
Breast discolouration		1	0
Breast discomfort		7	0
Breast engorgement		4	0
Breast haemorrhage		1	0
Breast induration		1	0
Breast oedema		1	0
Breast pain	3	18	0
Breast swelling		45	0
Breast tenderness		41	0
Nipple exudate bloody		1	0
Nipple pain		29	0
Nipple swelling		1	0
Cervix disorders NEC			
Cervix haemorrhage uterine		1	0
Erection and ejaculation conditions and disc	orders		
Ejaculation delayed		1	0
Ejaculation disorder		3	0
Ejaculation failure		2	0
Érectile dysfunction		49	0
Erection increased		4	0
Organic erectile dysfunction		18	0
Painful erection		1	0
Priapism		3	0
Retrograde ejaculation		3	0
Spontaneous penile erection		2	0
Fallopian tube and ovary infections and infla	ammations		
Noninfective oophoritis		1	0
Lactation disorders			
Galactorrhoea		2	0
Lactation disorder		2	0
Lactation puerperal increased		2	0
Suppressed lactation		21	0
Menopausal effects NEC			
Artificial menopause		2	0
Menopausal disorder		2	0
Menopausal symptoms		23	0
Menopause delayed			0
Premature menopause		2	0
Menopausal effects on the genitourinary tra	ct		-
Postmenopausal haemorrhage		22	0
Menstruation and uterine bleeding NEC			

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		Total	Fatal
Reproductive & breast disordeine & breast diso	rders cont'd		
Abnormal uterine bleeding		4	0
Abnormal withdrawal bleeding		2	0
Dysmenorrhoea		260	0
Intermenstrual bleeding		201	0
Menstrual discomfort		3	0
Menstrual disorder		377	0
Menstruation irregular		494	0
Premenstrual pain		18	0
Premenstrual syndrome		8	0
Retrograde menstruation		1	0
Withdrawal bleed		8	0
Menstruation with decreased bleeding			
Amenorrhoea		140	0
Hypomenorrhoea		115	0
Menstruation delayed		650	0
Oligomenorrhoea		28	0
Menstruation with increased bleeding			
Heavy menstrual bleeding		1073	0
Menometrorrhagia		3	0
Polymenorrhoea		144	0
Ovarian and fallopian tube cysts and neople	asms		
Ovarian cyst		9	0
Ovarian cyst ruptured		1	0
Polycystic ovaries		10	0
Ovarian and fallopian tube disorders NEC			
Ovarian enlargement		1	0
Ovarian haemorrhage		3	0
Ovarian necrosis		1	0
Ovarian vein thrombosis		2	0
Ovulation pain		13	0
Premature ovulation		2	0
Pelvic prolapse conditions			
Vaginal prolapse		1	0
Pelvis and broad ligament disorders NEC			
Adnexa uteri pain		20	0
Pelvic haematoma		1	0
Pelvic haemorrhage		10	0
Penile and scrotal infections and inflammat	ions		
Balanoposthitis		2	0
Penile disorders NEC (excl erection and eja	aculation)		
Penile blister	,	6	0
Penile burning sensation		1	0
Penile curvature		2	0
Penile discharge		2	0
Penile exfoliation		1	0
Penile haemorrhage		4	0
Penile oedema		2	0
Penile pain		1	0
Penis disorder		5	0
Peyronie's disease		4	0
Prostate and seminal vesicles infections an	d inflammations		Ŭ
Prostatitis		4	0
Prostatic neoplasms and hypertrophy			

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Reaction Name		Total	Fatal
Reproductive & breast disordaire & breast disord	lers cont'd		
Benign prostatic hyperplasia		2	0
Prostatic signs, symptoms and disorders NE	C		
Prostatism		1	0
Prostatomegaly		2	0
Reproductive tract disorders NEC (excl neop	lasms)		
Female genital tract fistula		1	0
Genital blister		3	0
Genital haemorrhage		11	0
Genital hyperaesthesia		1	0
Genital hypoaesthesia		2	0
Genital lesion		1	0
Genital paraesthesia		1	0
Genital ulceration		12	0
Perineal disorder		2	0
Reproductive tract infections and inflammatic	ons NEC		
Genital tract inflammation		2	0
Reproductive tract neoplasms NEC			
Genital cyst		1	0
Reproductive tract signs and symptoms NEC			
Genital burning sensation		6	0
Genital discomfort		3	0
Genital erythema		1	0
Genital pain		3	0
Genital rash		3 2	0
Pelvic discomfort		2	0
Pelvic pain		109	0
Perineal pain		1	0
Pruritus genital		6	0
Scrotal disorders NEC			
Scrotal dermatitis		1	0
Scrotal oedema		1	0
Scrotal pain		11	0
Scrotal swelling		5	0
Varicocele		1	0
Sexual function and fertility disorders NEC			
Dyspareunia		3	0
Female sexual dysfunction		1	0
Infertility		1	0
Infertility male		2	0
Male sexual dysfunction		1	0
Sexual dysfunction		6	0
Spermatogenesis and semen disorders			
Aspermia		1	0
Haematospermia		7	0
Semen discolouration		2	0
Testicular and epididymal disorders NEC			
Testicular disorder		5	0
Testicular mass		1	0
Testicular oedema		2	0
Testicular pain		86	0
Testicular retraction		1	0
Testicular swelling		12	0
Testis discomfort		1	0

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Reaction Name	Total	<u> Fatal</u>
Reproductive & breast disorders & breast	disorders cont'd	
Testicular and epididymal neoplasms		
Epididymal cyst		1 0
Testicular cyst		1 0
Uterine disorders NEC		
Adenomyosis		3 0
Endometriosis	3	32 0
Metrorrhoea		1 0
Uterine enlargement		1 0
Uterine haemorrhage	2	28 0
Uterine pain		6 0
Uterine neoplasms		
Uterine cyst		1 0
Uterine polyp		2 0
Uterine tone disorders		
Uterine spasm		9 0
Vaginal and vulval infections and inflam	mations	
Vulvovaginal inflammation		2 0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst		1 0
Vaginal cyst		8 0
Vulvovaginal disorders NEC		
Vaginal disorder		1 0
Vaginal haemorrhage	48	
Vaginal ulceration		6 0
Vulval disorder		2 0
Vulval haemorrhage	1	11 0
Vulval ulceration		4 0
Vulvovaginal ulceration		2 0
Vulvovaginal signs and symptoms		
Clitoral engorgement		1 0
Enlarged clitoris		1 0
Labia enlarged		2 0
Vaginal discharge	3	39 0
Vaginal lesion		4 0
Vaginal odour		1 0
Vulval oedema		1 0
Vulvovaginal burning sensation		7 0
Vulvovaginal discomfort		
Vulvovaginal dryness		6 0 5 0
Vulvovaginal erythema		1 0
Vulvovaginal pain		21 0
Vulvovaginal pruritus		
Vulvovaginal rash		8 0 2
Vulvovaginal rash Vulvovaginal swelling		5 0
Reproductive & breast disorders SOC TO	TAL 545	

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Apnoea	10	0
Apnoeic attack	1	0
Dyspnoea	5634	
Dyspnoea at rest	13	
Dyspnoea exertional	36	
Dyspnoea paroxysmal nocturnal	1	0
Grunting	2	0
Hyperventilation	80	
Hypopnoea	191	0
Hypoventilation	1	0
Irregular breathing	22	0
Mouth breathing	7	0
Orthopnoea	3	0
Respiration abnormal	82	0
Respiratory arrest	19	
Respiratory distress	8	0
Respiratory fatigue	6	
Sleep apnoea syndrome	19	
Tachypnoea	32	0
Bronchial conditions NEC	52	U
Bronchiectasis	14	0
Bronchospasm and obstruction	17	U
Aspirin-exacerbated respiratory disease	1	0
Asthma	467	0
Asthma exercise induced	407	0
Asthma exercise induced Asthma late onset	2	0
Asthma-chronic obstructive pulmonary disease overlap syndrome	2	0
Asthmatic crisis	5	0
Bronchitis chronic	1	0
Bronchospasm	14	
	28	0 2
Chronic obstructive pulmonary disease		0
Cough variant asthma Obstructive airways disorder	6 2	0
Reversible airways obstruction	4	
·	504	0
Wheezing	504	U
Conditions associated with abnormal gas exchange	2	0
Asphyxia	2	0
Hypercapnia		0
Hypoxia	57	1
Coughing and associated symptoms	_	0
Allergic cough	6	0
Cough	3228	
Haemoptysis	98	
Productive cough	153	
Sputum discoloured	7	0
Sputum increased	1	0
Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)		
Reflux laryngitis	2	0
Vocal cord thickening	2	0
Laryngeal spasm, oedema and obstruction		
Laryngeal oedema	2	0

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Reaction Name		Total	Fatal
Respiratory disorders espiratory disorders cont'd			
Laryngospasm		2	0
Stridor		18	0
Lower respiratory tract inflammatory and imi	nunologic conditions		
Alveolitis	•	2	0
Eosinophilic pneumonia		1	0
Pneumonia aspiration		22	4
Pneumonitis		20	1
Pulmonary sarcoidosis		1	0
Lower respiratory tract signs and symptoms			
Hiccups		39	0
Lower respiratory tract congestion		4	0
Lung opacity		5	0
Pleuritic pain		29	0
Pulmonary haemorrhage		5	1
Pulmonary pain		180	0
Rales		2	0
Mediastinal disorders			
Pulmonary hilum mass		1	0
Nasal congestion and inflammations			
Nasal congestion		405	0
Nasal inflammation		7	0
Rhinitis allergic		20	0
Rhinitis perennial		1	0
Nasal disorders NEC			
Epistaxis		1709	0
Intranasal hypoaesthesia		1	0
Nasal crusting		6	0
Nasal cyst		2	0
Nasal disorder		4	0
Nasal dryness		53	0
Nasal mucosal discolouration		1	0
Nasal odour		2	0
Nasal oedema		11	0
Nasal polyps		1	0
Nasal pruritus		8	0
Nasal septum deviation		1	0
Nasal septum perforation		1	0
Nasal ulcer		3	0
Neonatal hypoxic conditions		, and the second	·
Cyanosis neonatal		1	0
Gasping syndrome		2	0
Paranasal sinus disorders (excl infections ar	nd neonlasms)	_	Ŭ
Paranasal sinus haemorrhage	a neopiaeme)	5	0
Paranasal sinus hypersecretion		1	0
Paranasal sinus inflammation		2	0
Sinonasal obstruction		2 9	0
Sinus congestion		73	0
Sinus disorder		11	0
Sinus polyp		1	0
Parenchymal lung disorders NEC		'	U
Atelectasis		2	^
Emphysema		3 2	0
		1	0
Idiopathic pulmonary fibrosis		1]	U

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Reaction Name	Total	Fatal
Respiratory disorders espiratory disorders cont'd		
Interstitial lung disease	13	3 0
Lung consolidation	4	4 0
Lung cyst		1 0
Lung infiltration		1 0
Pulmonary alveolar haemorrhage		1 0
Pulmonary cavitation		
Pulmonary fibrosis	ļ ,	0 0
Pharyngeal disorders (excl infections and neople		
Oropharyngeal swelling		2 0
Pharyngeal erythema		3 0
Pharyngeal haemorrhage		
Pharyngeal hypoaesthesia	33	
Pharyngeal inflammation		1 0
	1-	
Pharyngeal oedema Pharyngeal paraesthesia	29	1
Pharyngeal swelling	228	
Pharyngeal ulceration	14	
Tonsillar disorder		1 0
Tonsillar erythema		0
Tonsillar haemorrhage		1 0
Tonsillar hypertrophy	57	1
Tonsillar inflammation	4	
Tonsillar ulcer	2	2 0
Pleural conditions NEC		
Pleural thickening		1 0
Pleural infections and inflammations		
Lupus pleurisy	2	2 0
Pleurisy	40	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	22	2 0
Pneumothorax	4	1 0
Pulmonary hypertensions		
Pulmonary hypertension	2	2 1
Pulmonary oedemas		
Acute lung injury	,	1 0
Acute pulmonary oedema		3 0
Acute respiratory distress syndrome		1 0
Pulmonary congestion	14	4 0
Pulmonary oedema	20	1
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis		1 0
Pulmonary embolism	1120	81
Pulmonary infarction	10	
Pulmonary thrombosis	19	1
Pulmonary venous thrombosis		
Respiratory failures (excl neonatal)		
Acute respiratory failure		1 0
Respiratory failure	16	
Respiratory signs and symptoms NEC	16	
		2 ^
Allergic respiratory symptom	13	
Diaphragmalgia		1
Painful respiration		
Respiratory symptom	16	6 0

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Reaction Name	Total	<u> Fatal</u>
Respiratory disorders espiratory disorders cont'd		
Suffocation feeling	4	4 0
Respiratory tract disorders NEC		
Aspiration		9 2
Chronic respiratory disease		9 2 2 1
Lung disorder		al o
Pulmonary mass	;	3 0
Respiratory disorder		
Respiratory tract congestion		5 0 7 0
Respiratory tract haemorrhage		1 0
Respiratory tract irritation		8 0
Respiratory tract oedema		1 0
Thoracic musculoskeletal disorders		
Respiratory muscle weakness		1 0
Tracheal disorders (excl infections and neoplasm		<u>'</u>
Tracheal fistula		1 0
Tracheal pain		3 0
Upper respiratory tract signs and symptoms		1 "
Aphonia	70	6 0
Catarrh	54	1
Choking	1.	
Choking sensation		8 0
Dry throat	228	
Dysphonia	110	
Increased upper airway secretion		3 0
Increased viscosity of upper respiratory secretic		
Laryngeal pain		1 0
Nasal discharge discolouration		
Nasal discomfort	9	3 0
Oropharyngeal blistering	22	
Oropharyngeal discomfort	30	
Oropharyngeal pain	3640	
Oropharyngeal plaque	0040	1 0
Paranasal sinus discomfort	5	
Rhinalgia	3	
Rhinorrhoea	1464	
Sinus pain	520	
Sneezing	408	
Snoring		5 0
Throat clearing		5 0
Throat irritation	175	
Throat lesion	17	1 0
Throat tightness	170	
Upper airway obstruction		1 0
Upper respiratory tract congestion		1 0
Upper-airway cough syndrome	24	
Yawning	6	
Vascular pulmonary disorders NEC		Ί ,
Pulmonary artery occlusion		1 0
Pulmonary vascular disorder		1 0
	2249	7 107
Respiratory disorders SOC TOTAL	2249	<u>/ 10/</u>

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u>Fatal</u>
Skin disorders		
Acnes		
Acne	75	0
Acne cystic	4	0
Dermatitis acneiform	7	0
Alopecias		
Alopecia	207	0
Alopecia areata	13	0
Alopecia totalis	1	0
Alopecia universalis	2	2 0
Androgenetic alopecia	1	0
Diffuse alopecia	3	0
Madarosis	2	2 0
Angioedemas		
Angioedema	281	0
Circumoral oedema	2	0
Idiopathic angioedema	3	0
Apocrine and eccrine gland disorders		
Anhidrosis	2	2 0
Cold sweat	1529	0
Hyperhidrosis	8268	0
Hypohidrosis	3	0
Miliaria	178	0
Night sweats	1677	0
Sweat discolouration	3	0
Sweat gland disorder	1	0
Bullous conditions		
Blister	407	0
Blister rupture	7	0
Blood blister	70	0
Dermatitis bullous	12	2 0
Dermatitis herpetiformis		2 0
Erythema multiforme	32	0
Oedema blister	1	0
Pemphigoid	18	0
Pemphigus	1	0
Stevens-Johnson syndrome	6	0
Toxic epidermal necrolysis	3	0
Connective tissue disorders		
Chronic cutaneous lupus erythematosus	1	0
Cutaneous lupus erythematosus	1	0
Dermatomyositis	3	0
Subacute cutaneous lupus erythematosus	1	0
Dermal and epidermal conditions NEC		
Acute febrile neutrophilic dermatosis	1	0
Dry skin	355	0
Macule	g	0
Myxoid cyst	1	0
Neutrophilic dermatosis	1	0
Pain of skin	835	0
Papule	87	
Peau d'orange	3	
Scab	20	
Scar pain	10	

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	DRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sensitive skin	530	0
Skin burning sensation	486	0
Skin discolouration	141	0
Skin discomfort	3	0
Skin disorder	21	0
Skin fissures	10	0
Skin fragility	1	0
Skin indentation	12	0
Skin induration	14	0
Skin laxity	1	0
Skin lesion	38	0
Skin necrosis	4	0
Skin odour abnormal	44	0
	3	
Skin plaque Skin reaction	219	0
Skin reaction Skin sensitisation		
	82	0
Skin swelling	80	0
Skin texture abnormal	1	0
Skin tightness	27	0
Skin warm	522	0
Skin weeping	5	0
Sticky skin	7	0
Target skin lesion	1	0
Transient acantholytic dermatosis		0
Yellow skin	25	0
Dermatitis and eczema		
Autoimmune dermatitis	1	0
Dermatitis	150	0
Dermatitis allergic	251	0
Dermatitis atopic	16	0
Dermatitis contact	15	0
Dermatitis diaper	2	0
Dyshidrotic eczema	6	0
Eczema	203	0
Eczema asteatotic	12	0
Eczema nummular	3	0
Eczema weeping	2	0
Hand dermatitis	5	0
Intertrigo	2	0
Perioral dermatitis	3	0
Prurigo	1	0
Rebound eczema	1	0
Seborrhoeic dermatitis	7	0
Skin irritation	116	-
Stasis dermatitis	3	0
Dermatitis ascribed to specific agent	3	U
Drug eruption	30	0
Drug reaction with eosinophilia and systemic sy		0
Fixed eruption	4	0
Palmar-plantar erythrodysaesthesia syndrome	1	0
Erythemas		
Erythema	2960	
Erythema ab igne		0

Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Palmar erythema	5	0
Exfoliative conditions		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	4	0
Exfoliative rash	13	0
Skin exfoliation	107	0
Granulomatous and deep cutaneous inflammatory conditions		
Granuloma annulare	2	0
Hyperpigmentation disorders		
Melanoderma	2	0
Skin hyperpigmentation	6	0
Solar lentigo	5	0
Hypertrichoses		
Hypertrichosis	1	0
Hypopigmentation disorders		
Skin depigmentation	7	0
Skin hypopigmentation	1	0
Vitiligo	11	0
Lipodystrophies		
Lipoatrophy	2	0
Lipohypertrophy	2	0
Nail and nail bed conditions (excl infections and infestations)		
Ingrowing nail	1	0
Nail bed disorder	2	0
Nail bed tenderness	1	0
Nail discolouration	9	0
Nail disorder	1	0
Nail hypertrophy	1	0
Nail necrosis	1	0
Nail pigmentation	1	0
Nail pitting	1	0
Nail ridging	5	0
Onychalgia	4	0
Onychoclasis	8	0
Onycholysis	1	0
Onychomadesis	1	0
Splinter haemorrhages	1	0
Panniculitides		
Erythema nodosum	21	0
Panniculitis	3	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	18	0
Lichen sclerosus	3	0
Parapsoriasis	1	0
Pityriasis rosea	34	0
Pityriasis rubra pilaris	2	0
Photosensitivity and photodermatosis conditions		
Photodermatosis	1	0
Photosensitivity reaction	131	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
Pigmentation changes NEC		

Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Pigmentation disorder	1	1 0
Pilar disorders NEC		
Hair colour changes		7 0
Hair disorder		1 0
Hair growth abnormal		5 0
Hair texture abnormal		5 0
Piloerection	3	37 O
Pseudofolliculitis		1 0
Trichodynia		5 0
Trichorrhexis		1 0
Pruritus NEC		
Itching scar		4 0
Pruritus	678	3 0
Pruritus allergic		1 0
Senile pruritus		1 0
Psoriatic conditions		
Guttate psoriasis	1	8 0
Psoriasis	14	
Pustular psoriasis		1 0
Purpura and related conditions		
Ecchymosis		4 0
Henoch-Schonlein purpura	1	0 0
Petechiae	24	
Purpura		0
Pustular conditions		
Acute generalised exanthematous pustulo	sis	1 0
Rash follicular		4 0
Rashes, eruptions and exanthems NEC		
Butterfly rash		7 0
Rash	720	0 0
Rash erythematous	193	
Rash macular	61	
Rash maculo-papular		55 0
Rash morbilliform		39 0
Rash papular	44	
Rash pruritic	158	
Rash rubelliform		1 0
Rash scarlatiniform		2 0
Rash vesicular		66 0
Systemic lupus erythematosus rash		7 0
Rosaceas		
Erythematotelangiectatic rosacea		1 0
Rosacea	3	80 0
Scaly conditions		
Pityriasis		6 0
Sebaceous gland disorders		
Seborrhoea		5 0
Skin and subcutaneous conditions NEC		
Adiposis dolorosa		1 0
Cutaneous symptom		7 0
Eosinophilic cellulitis		1 0
Skin mass		29 0
Skin and subcutaneous tissue ulcerations		.
SKIN AND SUDCUTANEOUS TISSUE UICERATIONS		

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	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Diabetic foot		_
Mucocutaneous ulceration	2	. 0
Pyoderma gangrenosum	2	. 0
Skin erosion	40	0
Skin ulcer	23	0
Skin cysts and polyps		
Dermal cyst	12	. 0
Skin dystrophies		
Skin wrinkling	2	. 0
Skin haemorrhages		
Haemorrhage subcutaneous	14	. 0
Skin haemorrhage	28	
Skin hyperplasias and hypertrophies	20	
Skin hypertrophy	1	0
Skin hypoplasias and atrophies	· ·	"
Skin atrophy	7	0
Skin striae	8	1
Skin injuries and mechanical dermatoses	0	
Decubitus ulcer	2	
	3	
Needle track marks	3	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1 1	_
Leukoplakia	1	0
Skin vascular conditions NEC		
Angiodermatitis	1	, ,
Skin oedema	3	0
Skin vasculitides		
Cutaneous vasculitis	8	
Hypersensitivity vasculitis	3	
Vasculitic rash	23	1
Skin vasomotor conditions		
Livedo reticularis	46	0
Telangiectasia and related conditions		
Spider naevus	2	. 0
Telangiectasia	3	0
Urticarias		
Chronic spontaneous urticaria	2	. 0
Cold urticaria	3	
Idiopathic urticaria	7	1
Mechanical urticaria	2	
Solar urticaria	1	<u> </u>
Urticaria	2008	0
Urticaria chronic	21	1
Urticaria contact	2	
Urticaria contact Urticaria papular	2	
Urticaria papulai Urticaria thermal	2	_
	5	1
Urticarial vasculitis	5	
Skin disorders SOC TOTAL	42426	1

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA 2		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Social circumstances		
Age related issues		
Childhood	1	0
Menarche	2	0
Menopause	17	0
Postmenopause	2	0
Bereavement issues		
Death of relative	1	1
Criminal activity		
Chemical submission	1	0
Dependents		
Sick relative	1	0
Dietary and nutritional issues		
Inadequate diet	1	0
Kosher diet	1	0
Disability issues		
Bedridden	63	0
Breast prosthesis user		0
Dependence on oxygen therapy	2	0
Disability	3	0
Hearing aid user	3 2	0
Hearing disability	1	0
Housebound	2	0
Immobile	39	0
Immobilisation prolonged	3	0
Impaired driving ability	3	0
Impaired work ability	14	0
Loss of personal independence in daily activities	3	0
Sight disability	16	0
Sitting disability		0
Walking disability	2 2	0
Educational issues		
Illiteracy	1	0
Employment issues		
Job dissatisfaction	1	0
Retirement	5	0
Stress at work	1	0
Family and partner issues		
Homosexual parent	1	0
Non-occupational and unspecified environmental problems		
Food contamination	1	0
Water pollution	3	0
Pregnancy related circumstances		
Breast feeding	5	0
Sexuality issues		
Anal sex	1	0
Homosexuality	1	0
Social issues NEC		
Blood donor	1	0
Contraindication to medical treatment	1	n
Contraindication to vaccination	2	0
Convalescent	1	0
Impaired quality of life	1	0
Refusal of vaccination	1	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco use		
Non-tobacco user	3	0
Tobacco user	2	0
Social circumstances SOC TOTAL	215	1

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Earliest Reaction Date: 03-Feb-1921 MedDRA Version: MedDRA		Cotol
Reaction Name	Total	<u>Fatal</u>
Surgical & medical procedures		
Anaesthesia and allied procedures Local anaesthesia	2	_
Nerve block	3 5	
	٥	0
Analgesia supportive care	1	_
Analgesic therapy	1	0
Antiinfective therapies		_
COVID-19 prophylaxis	1	0
COVID-19 treatment	6	0
Arterial therapeutic procedures (excl aortic)	4	_
Cerebral revascularisation	1	0
Coronary artery bypass	1	0
Autonomic nerve therapeutic procedures		_
Vagotomy	2	0
Blood and blood product treatment		_
Photopheresis	1	0
Breast therapeutic procedures NEC		_
Axillary lymphadenectomy	1	0
Bronchial and pulmonary therapeutic procedures		_
Airway secretion clearance therapy	1	0
Cardiac device therapeutic procedures		_
Pacemaker generated rhythm	1	0
Cardiac therapeutic procedures NEC		_
Pericardial excision	2	0
Contraceptive methods female		_
Contraception	1	0
Contraceptive diaphragm	3	
Oral contraception	1	0
Corneal and scleral therapeutic procedures		_
Corneal transplant	1	0
Dental and gingival therapeutic procedures		_
Dental care	1	0
Tooth extraction	1	0
Dietary and nutritional therapies		_
Fluid replacement	1	0
Medical diet	5	· ·
Nothing by mouth order	2	0
External ear therapeutic procedures		
Cerumen removal	2	0
Eye therapeutic procedures NEC		
Eye irrigation	3	0
Facial therapeutic procedures		
Face lift	2	0
Fallopian tube therapeutic procedures		
Fallopian tube operation	1	0
Fertility and fertilisation interventions female		
Ovulation induction	1	0
Gastrointestinal therapeutic procedures NEC		
Intestinal resection	1	0
Prophylaxis against gastrointestinal ulcer	1	0
Prophylaxis of nausea and vomiting	26	0
Gynaecological therapeutic procedures NEC		
Menstrual cycle management	1	0
Haematological therapeutic procedures NEC		

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Reaction Name		Total	Fatal
Surgical & medical procedures medical proc	edures cont'd		
Anticoagulant therapy		2	0
Haemofiltration		1	0
Head, neck and oral cavity therapeutic p	rocedures NEC		
Neck lift		1	0
Hormonal therapeutic procedures NEC			
Hormone replacement therapy		3	0
Hormone therapy		1	0
Immunisations			
COVID-19 immunisation		174	1
Immunisation		80	0
Tuberculosis immunisation		1	0
Induced abortions			
Abortion induced		1	0
Joint therapeutic procedures			
Hip surgery		1	0
Joint injection		1	0
Joint stabilisation		1	0
Knee operation		1	0
Large intestine therapeutic procedures			
Appendicectomy		5	0
Limb therapeutic procedures			
Foot amputation		1	0
Leg amputation		2	0
Limb immobilisation		24	0
Limb operation		7	0
Limb reattachment surgery		1	0
Toe amputation		4	0
Mastectomies			
Breast conserving surgery		2	0
Muscle therapeutic procedures			
Muscle relaxant therapy		2	0
Nasal therapeutic procedures			
Nasal irrigation		1	0
Nervous system therapeutic procedures	NEC		
Central nervous system stimulation		3	0
Orbit and globe therapeutic procedures			•
Eye muscle operation		1	0
Patient positioning		·	
Prone position		1	0
Prophylactic procedures NEC		· i	Ū
Anaphylaxis prophylaxis		3	0
Psychiatric therapies		Ĭ	Ū
Antidepressant therapy		1	0
Renal therapeutic procedures		· i	Ū
Dialysis		1	0
Skin and subcutaneous tissue therapeut	ic procedures NFC		J
Dermal filler injection	10 procedures 1420	1	0
Skin lesion excisions		'	0
Tattoo excision		1	0
Small intestine therapeutic procedures		'	0
lleostomy		2	0
Spine and spinal cord therapeutic proce	dures		U
	141 O3	1	0
Spinal operation		1	

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Reaction Name	Total	Fatal
Surgical & medical procedures cont'd		
Testicular and scrotal therapeutic procedures		
Testes exploration	1	0
Therapeutic procedures NEC		
Anaphylaxis treatment	3	0
Antiallergic therapy	1	0
Bed rest	19	0
Catheter management	2	0
Catheter placement	1	0
Fatigue management	1	0
Heat therapy	2	0
Hospitalisation	20	0
Immobilisation bandage	1	0
Injection	35	0
Interchange of vaccine products	1	0
Localised alternating hot and cold therapy	5	0
Manipulation	1	0
Mass excision	10	0
Medication dilution	1	0
Physical fitness training	2	0
Product used for unknown indication	1	0
Promotion of wound healing	1	0
Self-medication	1	0
Smoking cessation therapy	1	0
Specialist consultation	1	0
Stoma care	1	0
Therapeutic hypothermia	2	0
Therapy change	1	0
Transgender operation	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	1	0
Hysterectomy	1	0
Vascular therapeutic procedures NEC		
Thrombectomy	2	0
Venous therapeutic procedures		
Phlebotomy	2	0
Surgical & medical procedures SOC TOTAL	535	1

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Vascular disorders			
Accelerated and malignant hypertension			
Accelerated hypertension		1	0
Hypertensive crisis		9	0
Hypertensive emergency		9 2 2 2	0
Hypertensive urgency		2	0
Malignant hypertension		2	0
Tyramine reaction		1	0
Aneurysms and dissections non-site specific			
Aneurysm		9	2
Aneurysm ruptured		1	2 0
Artery dissection		1	0
Venous aneurysm		1	0
Aortic aneurysms and dissections			U
Acute arretic syndrome		1	0
Actite actite syndrome Aortic aneurysm		5	0
Aortic dissection		2	1
Aortic dissection Aortic intramural haematoma		1	0
		Į.	U
Aortic embolism and thrombosis		20	4
Aortic embolus		20	1
Aortic thrombosis		11	2
Aortic infections and inflammations		0	0
Aortitis		2	0
Aortic necrosis and vascular insufficiency			
Aortic occlusion		1	0
Aortic stenosis		2	0
Arterial infections and inflammations			
Arteritis		4	0
Giant cell arteritis		44	0
Blood pressure disorders NEC			
Blood pressure fluctuation		17	0
Labile blood pressure		2	0
Bruising, ecchymosis and purpura			
Achenbach syndrome		5	0
Circulatory collapse and shock			
Circulatory collapse		91	1
Distributive shock		2	0
Hypoperfusion		2 1	0
Hypovolaemic shock		1	0
Neurogenic shock		10	0
Peripheral circulatory failure		3	0
Shock		43	1
Shock symptom		5	0
Haemorrhages NEC			
Bloody discharge		8	0
Haematoma		80	0
Haemorrhage		581	2
Internal haemorrhage		21	0
Venous haemorrhage		7	0
Lymphangiopathies			
Lymphorrhoea		1	0
Lymphoedemas			
Lymphoedema		52	0
Non-site specific embolism and thrombosis		52	U
<u> </u>			

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Earliest Reaction Date: 03-Feb-1921	MedDRA Version: MedDRA 24.0		
Reaction Name		<u> Fotal</u>	Fatal
Vascular disorders Vascular disorders cont'd			
Arterial thrombosis		23	1
Embolism		239	3
Embolism arterial		3	0
Embolism venous		11	1
Microembolism		2	0
Paradoxical embolism		1	0
Thrombophlebitis migrans		1	0
Thrombosis		1112	20
Venous thrombosis		24	0
Non-site specific necrosis and vascular ins	ufficiency NEC		
Arterial occlusive disease	•	9	0
Arterial spasm		2	0
Arterial stenosis		1	0
Arteriosclerosis		3	0
Infarction		8	0
Ischaemia		9	0
Peripheral venous disease		4	0
Vascular compression		1	0
Vascular occlusion		1	0
Vasospasm		7	0
Non-site specific vascular disorders NEC			
Angiopathy		2	0
Arterial rupture		2 1	0
Capillary fragility		9	0
Collateral circulation		1	0
Haemodynamic instability		2	0
Hyperaemia		1	0
Neovascularisation		1	0
Superficial vein prominence		4	0
Vascular pain		91	0
Vascular rupture		1	0
Vascular wall discolouration		1	0
Vasodilatation		83	0
Vein collapse		1	0
Vein discolouration		4	0
Vein disorder		12	0
Vein rupture		13	0
Peripheral aneurysms and dissections			
Peripheral artery aneurysm		1	0
Peripheral embolism and thrombosis			
Blue toe syndrome		29	0
Deep vein thrombosis		824	7
Femoral artery embolism		2	0
lliac artery embolism		2	0
Jugular vein thrombosis		18	0
Pelvic venous thrombosis		13	1
Peripheral artery thrombosis		15	0
Peripheral embolism		8	0
Peripheral vein thrombus extension		1	0
Subclavian artery thrombosis		1	0
Subclavian vein thrombosis		1	0
Thrombophlebitis		88	0
Thrombophlebitis superficial		43	0

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Peripheral vascular disorders NEC Cyanosis 99 Erythromelalgia 50 Flushing 64 Hot flush 1820 Peripheral vascular disorder 7 Peripheral vasoconstriction, necrosis and vascular insufficiency 5 Dry gangrene	5 0
Venous thrombosis limb Peripheral vascular disorders NEC Cyanosis 99 Erythromelalgia Flushing 644 Hot flush 1820 Peripheral vascular disorder Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	5 0 5 0 0 0
Peripheral vascular disorders NEC Cyanosis 99 Erythromelalgia 59 Flushing 644 Hot flush 1820 Peripheral vascular disorder 79 Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	5 0 5 0 0 0
Cyanosis Erythromelalgia Flushing Hot flush Peripheral vascular disorder Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	5 C
Erythromelalgia Flushing Hot flush Peripheral vascular disorder Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	5 C
Flushing 64 Hot flush Peripheral vascular disorder Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	
Hot flush Peripheral vascular disorder Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	
Peripheral vascular disorder Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	
Peripheral vasoconstriction, necrosis and vascular insufficiency Dry gangrene	1 C
Dry gangrene	
, , , ,	
	1 C
Extremity necrosis	3 0
Iliac artery occlusion	1 C
Intermittent claudication	2 C
Ischaemic limb pain	4 C
Jugular vein occlusion	1 C
Peripheral arterial occlusive disease	3 0
Peripheral artery occlusion	7 C
Peripheral coldness 115	
Peripheral ischaemia 2	3 2
Poor peripheral circulation 4	1 C
Raynaud's phenomenon 11:	2 0
Phlebitis NEC	
Phlebitis 4	5 0
Phlebitis superficial	7 C
Site specific embolism and thrombosis NEC	
Brachiocephalic vein thrombosis	1 C
Site specific vascular disorders NEC	
Pallor 370	
Plethoric face	1 C
Varicose veins NEC	
Bleeding varicose vein	1 C
Spider vein 10	
Varicophlebitis	4 C
Varicose vein 9	3 0
Vascular hypertensive disorders NEC	
Diastolic hypertension	1 C
Hypertension 68	e c
Labile hypertension	ı c
Systolic hypertension	<u>2</u> 0
	3 0
White coat hypertension	
Vascular hypotensive disorders	
	3 C
Hypotension 44	5 C
Orthostatic hypotension 3	el c
Vascular malformations and acquired anomalies	
Arteriovenous fistula	1 c
Vasculitides NEC	
Diffuse vasculitis	ıl 1
MAGIC syndrome	3 1
Vasculitis 10	
Vena caval embolism and thrombosis	
Vena cava thrombosis	3 1
Vascular disorders SOC TOTAL 954	50

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
TOTAL REACTIONS FOR DRUG	695214	831
TOTAL REPORTS	188589	
TOTAL FATAL OUTCOME REPORTS		831